

Federal Court



Cour fédérale

Date: 20231207

Docket: T-1831-22

Ottawa, Ontario, December 7, 2023

PRESENT: Case Management Judge Benoit M. Duchesne

BETWEEN:

**BOEHRINGER INGELHEIM (CANADA) LTD. and BOEHRINGER
INGELHEIM INTERNATIONAL GMBH**

Plaintiffs

and

SANDOZ CANADA INC.

Defendant

AND

Court File No. T-1842-22

BETWEEN:

**BOEHRINGER INGELHEIM (CANADA) LTD. and BOEHRINGER
INGELHEIM INTERNATIONAL GMBH**

Plaintiffs

and

SUN PHARMA CANADA INC.

Defendant

AMENDED ORDER

[1] The Plaintiffs Boehringer Ingelheim (Canada) Ltd. and Boehringer Ingelheim International GmbH (together “BI” or the “Plaintiffs”) and the Defendants Sandoz Canada Inc. (“Sandoz”) and Sun Pharma Canada Inc. (“Sun”, and together, the “Defendants”) are engaged in separate proceedings commenced pursuant to subsection 6(1) of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the “Regulations”).

[2] The actions concern the Plaintiffs’ allegations that the Defendants’ making, constructing, using, and/or selling of orally administered empagliflozin tablets containing 10 mg or 25 mg empagliflozin in accordance with the abbreviated new drug submission (“ANDS”) they filed with the Minister of Health would directly or indirectly infringe or induce the infringement of various claims of the Plaintiffs patents bearing numbers 2,557,801, 2,606,650, 2,696,558, 2,751,833, 2,752,435 and 2,813,661.

[3] The Defendants argue that each of these patents and their claims are and always have been invalid, void, and of no force and effect on the various grounds pleaded in their respective statements of defence and counterclaims.

[4] The parties agreed to the terms of a protective order that was issued on February 15, 2023. The protective orders issued in each proceeding are identical except for the named Defendant and the court file number (the “Protective Orders”).

[5] The parties exchanged affidavits of documents and Schedule 1 productions in accordance with the scheduling order then in force. BI redacted the content of some of the documents

disclosed and produced in their affidavits of documents, and marked its productions from numbers 33 to 101, inclusively, that are described in BI's affidavits of document as "R&D documents" as "Solicitors' Eyes Only" ("SEO") documents that cannot be disclosed to the Defendants' in-house counsel although they can be disclosed to others as set out in the Protective Orders.

[6] The Defendants challenge BI's redactions and argue that the documents marked as SEO are improperly marked as SEO documents.

[7] BI has brought a motion by which it seeks an Order:

- a) dismissing the Defendants' challenge to documents designated by BI as "Solicitors Eyes Only" pursuant to clauses 4(b) and 27 the Protective Orders issued in these actions; and,
- b) dismissing the Defendants' challenge to the redactions made by BI to certain production documents pursuant to clause 11 of the Protective Orders issued in these actions.

[8] BI had also sought an Order compelling the production of the ANDS information of Sandoz and Sun that is identified in Schedule "C" to BI's notice of motion. That issue was addressed by an undertaking given by the Defendants in advance of the hearing of this motion.

[9] For the reasons that follow, BI's motion is granted and the Defendants' challenges as to redactions and SEO designations are dismissed.

I. REDACTIONS

A) The Basis for the Redactions

[10] Paragraph 11 of the Protective Orders also allow the parties to redact "Information which is not relevant to this proceeding" from documents that are otherwise disclosed and produced.

[11] BI made redactions to some of its productions on the basis that the redacted content contained personal information that is either protected pursuant to European Union General Data Protection Regulations 2016/79 (the "GDPR") or is other information that is not relevant to the issues pleaded.

[12] The parties' solicitors exchanged various correspondence with respect to the redactions. The parties could not reach an understanding on the appropriateness of all of the redactions made by BI.

[13] On February 27, 2023, the Plaintiffs delivered a 51-page listing to the Defendants that contained all of the redactions they had made to their disclosed and produced documents. The listing identified each document, the locus of the redaction on each document, the nature of the redacted information, and the basis for the redaction.

[14] From the Plaintiffs' perspective, all of the redactions made are in accordance with the agreed upon terms of paragraph 11 of the Protective Orders and redact irrelevant information that could properly be redacted from the produced documents. BI has since withdrawn 32 redactions it had made that were indicated as the name/signature of a document's author(s) who was a BI employee but not an inventor of any patent at issue.

[15] The Defendants' position is more nuanced. The Defendants have led evidence through Kristin Marks, one of their external solicitors of record, that contains her observations of the redactions listing delivered by the Plaintiffs on February 27, 2023. Her observations are that BI's redactions are all based on relevance, and that there are 117 rows (by her count) in which "not an inventor on any patent at issue" is provided as a basis for the redactions. Ms. Marks deposes that the basis of the BI redactions can be roughly categorized as being one of the following:

- 1 Names of individuals conducting experiments/testing/clinical trial redacted on basis they are not named inventors.
- 2 Test results redacted on the basis that they are purportedly not relevant.
- 3 Document author (resolved shortly before motion materials were filed).
- 4 Contact information for individuals.
- 5 Laboratory notebook witness/verifier.
- 6 Patient data.

[16] The Defendants relented on their challenges following the Plaintiffs' decision to withdraw the 32 redactions referred to above and have withdrawn their initial challenge to the redactions by withdrawing their challenges that fall within categories 4, 5, and 6, identified by them, above.

[17] What is left to be determined on this motion as to redactions are those redactions that the Defendants categorize as falling within categories 1 and 2 above, specifically, those redactions being ostensibly made because the information redacted consists of names of individuals conducting experiments/testing/clinical trial redacted on the basis they are not named inventors, and test results redacted on the basis that they are not relevant to the issues framed by the pleadings.

B) Analysis

1) The Applicable Standard

[18] Shortly after the hearing of this motion, Associate Judge Horne issued his reasons in *Boehringer Ingelheim (Canada) Ltd. v Pharmascience Inc.*, 2023 FC 584 (CanLII) (“*BI v Pharmascience 2023*”), a decision in which he considered the general principles applicable to the use of redactions in this Court and in which he restated the proper use of redactions in time-compressed proceedings initiated pursuant to subsection 6(1) of the *Regulations*. As held by Associate Judge Horne on the basis of unimpeachable authority, the general principle that governs is that no redactions should be made to a document that contains relevant information. Consistent with that general principle, his Honour remarked at paragraph 11 that, “It is self-

evident that redactions based on relevance should be exceptional, sparingly applied, and clearly explained”.

[19] Associate Judge Horne exposed the legal principles relating to redactions as explained in the unreported *Pharmascience Inc v Meda, AB* (Court file T-815-17) decision dated May 4, 2020 (“*Meda*”), by Prothonotary Aylen (as she then was) by reiterating her words as follows with approval:

[15] The starting point to any documentary discovery is that a party is obligated to produce relevant documents in their entirety. The redaction of information from a relevant document is therefore exceptional. However, there are circumstances where this Court has recognized that the redaction of information may be permissible. Partial production may be made where the producing party can satisfy the Court that: (a) the redacted portion is clearly irrelevant to the issues in dispute; and (b) the redacted portion would clearly not assist in properly understanding those parts of the documents which are relevant. Redactions should only be resorted to, however, where important confidentiality concerns exist. Where the parties have enhanced confidentiality protections (such as through a protective agreement or a protective order), the case for redactions is weaker [see *Eli Lilly Canada Inc v Sandoz Canada Incorporated*, 2009 FC 345 at para 14; *Janssen Inc v Apotex Inc*, 2018 FC 407 at para 9].

[16] Accordingly, any party that produces a document in redacted form bears the burden of demonstrating the propriety of the redactions made – namely, that the redacted information is clearly irrelevant to the issues in dispute, the redacted information would clearly not assist in properly understanding those parts of the documents which are relevant and that redactions were made as a result of an important confidentiality concern. In considering the propriety of any redactions, the Court must engage in a balancing exercise, keeping in mind the rights of both parties, particularly in the face of any added protective measures in place beyond the implied undertaking rule.

[17] In terms of the “clearly irrelevant” standard, relevance must be determined by the issues and facts as framed in the pleadings. The disclosure of documents is a matter of relevance and not of discretion (*Novopharm Ltd v Eli Lilly Canada Inc*, 2008 FCA

287 at para 56). Where a relevancy determination must be made by the Court, a fair bit of latitude may be accorded to the inquiry and the tendency is to broaden discovery [see *Owen Holdings Ltd v Canada*, 1997 CanLII 16702 (FCA), [1997] 3 CTC 351 at para 20 (FCA)].

[18] In the discovery context, a question will be relevant when there is a reasonable likelihood that it might elicit information which may directly or indirectly enable the party seeking the answer to advance its case or to damage the case of its adversary, or which fairly might lead to a train of inquiry that may either advance the questioning party's case or damage the case of its adversary [see *Canada v Lehigh Cement Limited*, 2011 FCA 120 at para 34]. These same principles apply in considering the potential relevance of redactions made by the Defendants.

[19] However, it is important to keep in mind, however, that the threshold on this motion is lower. The Court is not asked to determine whether redacted information is irrelevant, but rather whether the redacted information is clearly irrelevant. In the criminal law context, the "clearly irrelevant" standard has been set quite low [see *R v Stinchcombe*, 1991 CanLII 45 (SCC), [1991] 3 SCR 326; *R v Hassan*, 2014 ONSC 1345 at para 12].

[20] Associate Judge Horne confirmed in *BI v Pharmascience 2023* at paragraphs 15 and 16 as had Prothonotary Ayles (as she then was) that the standard to be applied when considering the appropriateness of redactions is whether the information that is redacted is "clearly irrelevant" rather than simply "not relevant":

[15] The clearly irrelevant standard should apply to all redactions for relevance. The starting point is that if a document is relevant, it must be produced in its entirety. Redactions can be appropriate, but should be sparingly used to avoid disputes during the discovery phase of an action. In the context of redactions for relevance, clearly irrelevant is a high standard. It requires that it be self-evident, obvious or without doubt that the portion of a document sought to be concealed from the adversary would not assist in properly understanding those parts of the documents which are relevant. If relevance is debatable, the place for that debate is during the examinations for discovery, and any subsequent motions to compel.

[16] Where a redaction is made to protect an interest in confidential information, the producing party is expected to adduce evidence to demonstrate that harm could arise if the document was produced in an unredacted form. The discovery process inherently requires parties to disclose information to each other that would otherwise be securely stored in the company archives. If the recipient can be (or is expected to be) trusted to make limited and proper use of documents generally, the party intending to redact certain information based on confidentiality concerns must explain and justify why that excerpt must be treated differently. There has to be a good reason why a portion of an otherwise relevant document should not be disclosed, including why the implied undertaking rule and/or the terms of any protective order are insufficient to address any confidentiality concerns.

[21] When the redactions to be considered also involve personal information that, if disclosed, would cause significant harm to the producing party or would infringe public interests deserving of protection such as the protection of privacy and personal information pursuant to domestic or foreign statute, then the “clearly irrelevant” standard should be applied flexibly (*BI v Pharmascience 2023* at paras. 43 to 45):

[43] If I was to paraphrase the test for redactions based on relevance, it would be that if a document is relevant, there has to be a really good reason to conceal part of it. The Federal Court should, as a matter of comity, permit European litigants to discharge their documentary disclosure obligations in a manner that will not result in a contravention of foreign privacy law if it is reasonably possible to do so. If personal information may not be clearly irrelevant, but is of such trivial relevance that it would not assist in the determination of the issues and redaction would not prejudice the receiving party, the Court should flexibly apply the clearly irrelevant standard to permit compliance with the GDPR and BDSG.

[44] There is not always a bright line that separates the relevant from the irrelevant. What is relevant can be the subject of good faith debate between the parties, and involve judgment calls by the Court to resolve the issue. An issue that was not addressed by Dr Moelle or Justice Perell is who is the final arbiter of relevance for the purposes of compliance with the GDPR and BDSG, specifically what happens if a European party has a good faith

belief that certain personal information should be redacted, but a Canadian court disagrees, and is inclined to compel production.

[45] Based on the record I have, it is difficult to accept that an order from a Canadian court compelling production of certain personal information, after a contested motion, would not satisfy the necessity and balancing of interests tests described above. Put another way, if a European party states that a portion of a document should be redacted, a Canadian court is not powerless to disagree, and may compel production. Of course, any such order should consider and apply what the GDPR and BDSG require.

[22] The Court asked the parties to make limited written submissions regarding the impact of *BI v Pharmascience 2023*, on this motion in light of BI's argument that the redactions are appropriate, that the applicable standard to determine the validity of the redactions is relevance only, and its evidence that some of the redactions at issue redact personal information that should be protected and not disclosed by BI pursuant to GDPR.

[23] BI argues that *BI v Pharmascience 2023* is a decision delivered in a context in which the parties did not have a governing protective order that set out an agreed upon process to redact information from relevant documents, a party's entitlement to redact, or the legal test to be applied to the redactions. As a result, the *BI v Pharmascience 2023* decision and the cases cited within it are argued as being limited to those cases where redactions of irrelevant information is dictated by compliance with the *Federal Court Rules* only and the common law processes contained within them, and find no application on this motion because of the existence of the Protective Orders.

[24] BI further argues that the agreed-upon approach to redactions and the challenges thereto is not modified by *BI v Pharmascience 2023*. As such, the "clearly irrelevant" standard discussed

as a general principle in *BI v Pharmascience 2023* is not applicable to this motion. Instead, the Court must determine if the redactions are “not relevant to this Proceeding” in accordance with the standard of “relevance” contemplated by the parties and set out in the Protective Order.

[25] I disagree with the Plaintiffs.

[26] Neither the Protective Orders nor the parties’ agreement as to their terms modify the threshold for appropriate and proper redactions as contemplated by the *Rules* and the applicable jurisprudence. The concepts of relevance in discovery and the justification for redactions from otherwise relevant documents remain unchanged by the issued Protective Order: the “clearly irrelevant” standard remains the governing standard upon which the appropriateness of redactions is to be determined.

[27] Protective Orders are issued because the party seeking the order can demonstrate that the information that is the subject of the enhanced protection sought through the protective order has been treated at all relevant times as confidential and, that on a balance of probabilities, its proprietary, commercial and scientific interests could reasonably be harmed by the disclosure of the information through discovery without the enhanced protection afforded by the protective order (*Canadian National Railway Company v. BNSF Railway Company*, 2020 FCA 45 (CanLII), [2020] 3 FCR 124, at para. 22). The essence of a protective order in general and of the Protective Orders in this case, is to enhance the protections provided by the deemed undertaking rule with respect to the persons to whom the information that is protected by the order may be disclosed. In this sense protective orders apply to limit and circumscribe how and with whom

the information covered by the protective order that is disclosed during the discovery stage of an action may be shared (*Canadian National Railway Company v. BNSF Railway Company*, 2020 FCA 45 (CanLII), [2020] 3 FCR 124, at para. 17). Limiting who may have access to and see the disclosed and produced information through a protective order does not change the requirements of disclosure or production themselves as set out in the *Rules*.

[28] There is no suggestion that the rules of discovery set out in the *Rules* or that the *Rules* themselves have been ousted altogether by the Protective Orders. The Protective Orders in this case refer to the *Rules* repeatedly with respect to the concepts of discovery information, affidavits of documents, “documents” and how they are explicitly defined in Rule 222(1) of the *Rules*, as well as “examinations” as defined by Rule 87 of the *Rules*. By specifically referring to and explicitly and implicitly resting on the *Rules* themselves it is apparent that the parties’ reference to a “document” as referred to in Rule 222(1) also includes how documents are to be produced through the application of Rules 223 to 232 and 295 as explicitly referred to in Rule 222(1) and, more importantly, in Rule 222(2) with respect to the notion of relevance as defined therein.

[29] The scope of documentary relevance as contemplated by the Protective Orders remains unchanged from that set out in Rule 222(2) just as the scope of relevant questions on an examination remains unchanged from that set out in Rule 240. It follows that the scope of what is not relevant and can be redacted would also remain unchanged by the terms of a Protective Order.

[30] Accordingly, the basis for redactions on the basis of an absence of relevance to the issues as framed by the pleadings remains the “clearly irrelevant” basis reiterated by Associate Judge Horne in *BI v Pharmascience 2023*, considered in light of a flexible approach to the “clearly irrelevant” threshold to permit compliance with privacy legislation in Canada and elsewhere when the redacted information is of such trivial relevance that it would not assist in the determination of the issues, and, the redaction would not prejudice the receiving party.

[31] BI led evidence on this motion through the affidavit of Constantine Karbaliotis, an expert in privacy protection and international privacy laws, to establish that their redactions on the basis of the protection of personal information is required because of BI’s requirement to comply with the GDPR. The Defendants led the expert opinion of Sibylle Gierschmann on the issue of the GDPR and its application. Mr. Karbaliotis evidence and Ms. Gierschmann’s opinion are consistent with respect to the GDPR despite their differences in how it should be applied here.

[32] The GDPR evidence before me is generally consistent with the GDPR evidence that was summarized by Associate Judge Horne in *BI v Pharmascience 2023* at paragraphs 17 to 45. Given the consistency of the evidence led with respect to the GDPR and its application in Canada as set out in *BI v Pharmascience 2023* and on this motion, I share Associate Judge Horne’s views as to how the GDPR applies as described in *BI v Pharmascience 2023*, at para. 42:

[42] Having regard to all of the above, I do not perceive a real conflict between the Court’s general approach to redactions based on relevance, and what would be required for compliance with the GDPR and BDSG. If a party can establish that information proposed to be redacted from a document serves no legitimate purpose in resolving the issues, and disclosure of the

information would cause significant harm to the producing party or would infringe public interests deserving of protection, that would justify a redaction for both relevance and compliance with the GDPR and BDSG.

(the emphasis is mine).

[33] For the reasons given above, the appropriateness of BI's redactions will be determined on the basis of the "clearly irrelevant" standard that requires the demonstration that it is self-evident, obvious or without doubt that the portion of a document be redacted and concealed from the adversary would not assist in properly understanding those parts of the documents which are relevant.

[34] Where the redactions are made with respect to personal information that may not be clearly irrelevant, but is of such trivial relevance that it would not assist in the determination of the issues and redaction would not prejudice the receiving party, the "clearly irrelevant" test will be applied flexibly to permit compliance with the GDPR.

2) The GDPR / Relevance Redactions

[35] BI argues that its GDPR redactions can be grouped as follows:

- a) Signatures, names, user names, or other forms of information within a lab notebook or test results that if unredacted would disclose the identity of an individual who is not an inventor on any patent at issue, and had no relevant involvement to any issue in dispute in either action (BI100036, BI100065, BI100095; BI100101 (page 9));

- b) The name within an experimental record which discloses the identity of an individual who is not an inventor on any patent at issue, was simply carrying out the experiment (i.e., as a technician) on behalf of the indicated inventor; and had no relevant involvement to any issue in dispute in either action (BI100068 (page 1));
- c) Signatures, names, contact numbers, or other forms of information within a clinical trial document (report or protocol) which discloses the identity of an individual who is not an inventor on any of the patents at issue, and had no relevant involvement to any issue in dispute in either action (BI100112 (pages 1 and 25-27), BI100114 (pages 1 and 24), BI100115 (pages 2-4, and 69-72); and
- d) Redaction of personal, identifying information of a patient involved in a clinical trial, such as date of birth, age, or date they enrolled in various phases of the clinical trial (BI100114 page 573).

[36] BI argues that its redactions are not based on the GDPR but on “relevance” as set out in paragraph 11 of the Protective Orders. It argues that what remains redacted has no relevance to any issue in dispute because the redactions are only to the identifying information like names, signatures, and phone numbers of individuals with minimal and non-material involvement with the work relating to the patents, and thus with no relevance to any pleaded issue.

[37] BI has provided the Court with representative documents for the purposes of determining the appropriateness of the redactions based on relevance. All other documents similarly redacted

on the basis of relevance but not submitted for the Court's review should follow the determinations made on the basis of the submitted representative documents. The representative documents are identified as documents BI100036, BI100065, BI100095 and BI100101 (page 9). These representative documents are said to speak to the redactions set out in the documents identified as BI100033-0059, BI100088-099 and BI1000101 identified by the Defendants in Appendix 1 of their written representations in green highlight as being those redactions that are still in issue in this category of redactions.

[38] BI has the burden of establishing that its redactions are appropriate. BI tendered the affidavit of Haris Hadzimuratovic, a BI employee, who deposes that BI instructed its external legal counsel to redact the following from in its productions in order to comply with the GDPR:

- i. The names of BI employees who had no or minimal involvement with the work relating to the patents at issue in this action. This includes, for example, the names and positions of technicians who conducted experiments under the supervision of inventors or other BI employees who had substantial involvement in the project;
- ii. The names and contact information of individuals from third-party organizations (i.e., non-BI employees);
- iii. Phone numbers, fax numbers and email addresses; and
- iv. Patient age, sex, date of birth, enrolment site, or other potentially identifying information in documents relating to clinical trials.

[39] Mr. Hadzimuratovic deposes that the representative redacted documents produced by BI as documents BI100036, BI100065, BI100068, BI100095, BI100101, BI100112 (pages 1 and 25-27), BI100114 (pages 1 and 24), and BI100115 (pages 1-4 and 69-72) were redacted in accordance with the instructions provided.

[40] I have reviewed the representative documents as well as the pleadings in light of Mr. Hadzimuratovic's affidavit.

[41] The Defendants contest Mr. Hadzimuratovic's affidavit and its content through the affidavit of Sibylle Gierschmann on the issue of the GDPR and its application. Ms. Gierschmann agrees with Mr. Hadzimuratovic's affidavit generally, but takes issue with his failure to apply the GDPR to this proceeding. She holds the opinion that Mr. Hadzimuratovic's evidence is unclear as to whether the GDPR bans BI from disclosing the names of the persons that have taken part in the development of the patented inventions, whether as an inventor or not in the course of pre-trial proceedings. In any event, Ms. Giershmann opines that the GDPR does not prohibit the disclosure of personal data in pre-trial discovery if BI wished to base its disclosures on article 6(4) or article 6(1)(f) of the GDPR. I note that Ms. Giershmann's mandate was to assume that the information redacted by BI on the basis of the GDPR would be considered relevant in these proceedings because the Defendants wish the information to obtain an understanding of who did what in relation to inventions claims, to match the names found in different documents and to identify potential witnesses for trial, thereby making the information "necessary" for the litigation. The assumption relied upon by Ms. Giershmann overstates what

may be relevant in this proceeding, is flawed and in my view taints her opinion and conclusions as unreliable for present purposes.

[42] The Defendants do not contest the nature of the information redacted by BI as described in its February 27, 2023, 51-page redaction listing that was provided to them. In fact, the Defendants have led no probative or compelling evidence to support their argument that BI's redactions are inappropriate.

[43] I have no compelling reason to doubt that the redactions that were made by BI were made for any reasons other than as described in BI's February 27, 2023, 51-page redaction listing that is in the evidence before me.

[44] Documents BI BI100033 and 0036 reflect the redaction of the name of the person who witnessed the recording of data by the person who recorded the data set out in a laboratory notebook. There is no suggestion that these recorded data points are incorrectly recorded such that the identity of the witness to the recording of data could be relevant in any way. These redactions, ostensibly on the basis of BI's compliance with the GDPR, are in my view appropriate. The name of the witness is clearly irrelevant to the proceedings whether prohibited by the GDPR or not.

[45] The contested redaction on document BI100039, was made to redact the name of the individual responsible for the indicated analysis who is not an inventor. In light of the pleadings,

it is my view that the name of the individual responsible for the indicated analysis is clearly irrelevant.

[46] The contested redaction on document BI000043, 44, 45, and 67 is with respect to the signature of the individual entering the lab notebook entry as well as the name of the individual who printed the notebook entry but who are not an inventor on any patent in issue. These redactions, ostensibly on the basis of BI's compliance with the GDPR, are in my view appropriate in light of the pleadings. The signature and the name of the person who entered the entry and the name of the person who printed the notebook entry are clearly irrelevant to the proceedings whether prohibited by the GDPR or not.

[47] The contested redactions on documents BI000049, 50, 51, 52, 53, 54, 55, 56, 57, 58, and 59, with respect to the header and footer information that is a data directory containing identifying information of an individual who is not an inventor as well as the individual's signature are appropriate. Such information is clearly irrelevant to the issues raised in the pleadings or to the understanding of the documents.

[48] The contested redaction at document BI100062 of the name of the user analyzing a sample but is not an inventor is appropriate. Although the redaction was ostensibly on the basis of BI's compliance with the GDPR, the name of the analysing user is clearly irrelevant in light of the pleadings, whether prohibited by the GDPR or not.

[49] The contested redactions at documents BI100068, 69, 70, 71, 72, 73, 74, 75, 76, and 77 are of the name of the person who carried out an experiment but is not an inventor. Although the redactions are ostensibly on the basis of BI's compliance with the GDPR, the name of the persons executing the experiments when they are not an inventor is clearly irrelevant in light of the pleadings. The redactions are appropriate.

[50] The contested redactions at documents BI100088, 89, 96, 97, 98, 99, and 101 of the user name of a user who is not an inventor of any patent at issue is appropriate. No evidence has been led to suggest that the user name is any way relevant to any issue in the proceedings. The user name is clearly irrelevant.

[51] The contested redactions on documents BI10000102, 103, 104, 105, 106, 108, 109, 110, 111, 112, 113, 114, and 115 pertaining to the names of the clinical trial principal investigator, investigator, trial clinical monitor, data manager, individual who conducted statistical analysis, investigator, person responsible at a listed Study Centre are appropriate redactions. The identity of these persons is clearly irrelevant to the issues raised in the proceedings.

3) The Irrelevant Test Results Redactions

[52] BI argues that the remaining challenged redactions are restricted to redactions based on irrelevant test results pertaining to SGLT2 irrelevant compounds and to SGLT1 inhibition testing.

[53] Although SGLT-2 inhibitor testing is at issue insofar as the patents concern aspects of SGLT-2 inhibitor testing, the testing relevant to the proceedings can only relate to the claims that are asserted by BI and challenged by the Defendants on the basis of the allegations made by the parties in their pleadings. Testing results relating to compounds that are other than those set out in the claims and raised in the pleadings are clearly irrelevant. It follows that the redactions made to documents BI000049, 50, 51, 52, 53, 54, 55, 56, 57, 58, and 59 that conceal test results for compounds other than the compounds at issue are appropriate as those test results are clearly irrelevant on the basis of the record before me.

[54] SGLT-1 inhibition testing is not an issue raised in the pleadings in this proceeding. Any test results purporting to deal with SGLT-1 inhibitors is clearly irrelevant. The Defendants' challenges to redactions based on such tests are therefore dismissed.

II. SEO DESIGNATIONS

A) The Basis for the SEO Designations

[55] BI argues that the criteria required for "Information" as defined in the Protective Orders to be designated as Confidential or SEO in compliance with the Protective Orders are explicit in the Protective Orders themselves. SEO Information must be: (i) Information that the Producing Party in good faith believes is maintained as confidential; (ii) Information that the Producing Party in good faith believes to be of a "particularly sensitive nature" or of a "commercially valuable nature to the Receiving Party"; and (iii) *inter alia*, Information that is scientific or technical.

[56] The Plaintiffs' productions included documents marked as SEO which contain scientific and technical Information which is maintained as confidential by BI, and which BI considers to be particularly sensitive: these productions are described as "R&D Documents".

[57] BI asks this Court to reject the Defendants' challenges to their SEO designation of productions 33 to 101 of their affidavits of documents within the meaning of the Protective Orders.

[58] BI takes issue with the Defendants' alleged failure to comply with the designation challenge process set out at paragraph 27 of the Protective Orders. BI argues that the Defendants have not served a written challenge or challenges to the SEO designations that "particularly identifies the information that the [Defendants] contend should be designated differently" as is required by paragraph 27 of the Protective Orders. By failing to do so, in their argument, there is no clear or principled basis upon which to challenge the designation made by BI.

[59] BI also argues that other aspects of the paragraph 27 challenge process such as engaging in good faith efforts to attempt to resolve the designation dispute on an informal basis are not satisfied by the Defendants with the result that their designation challenges should be dismissed.

[60] The Defendants argue that it is not they but BI who failed to comply with the requirements of paragraph 27 of the Protective Orders.

[61] What is apparent from the record before me is that the parties and their solicitors have been at odds from the outset of these proceedings. The record shows overly strident, accusatory, and needlessly provocative correspondence from and between the solicitors for the parties rather than joint meaningful efforts to attempt to resolve issues as they arise. Similar accusatory statements directed solely at the subjectively appreciated conduct of the adverse parties' solicitors were gratuitously made during the hearing of this motion. Submissions replete with accusations or insinuations of solicitor misconduct are unhelpful, are often not warranted by the facts, and more often than not reflect poorly on the solicitors and the parties making them. This is not to say that there is no place for such observations when appropriate. That place is more often than not in costs submissions.

[62] The Defendants have not actually led evidence as to the basis of their SEO designation challenge other than as argued in their written representations. The Defendants seek to argue that BI has not used the SEO designation judiciously but rather that they have used the SEO designation in an abusive and unreasonable manner by marking approximately 70 documents contained in their affidavits of documents as containing SEO information pursuant to the Protective Orders. I interpret the Defendants' complaint considered in its most favourable light as being that there are more SEO designations than they could perhaps have anticipated and such a large number of SEO designations is not made in good faith.

[63] The Court is nevertheless satisfied that the Defendants have despite themselves identified with sufficient broad brush particularity for the purposes of this motion that the information contained in documents described as internal BI documents pertaining to the development of the

inventions contained in the patents at issue were improperly designated as SEO documents on the basis of an abuse of right.

B) Analysis

1) The Applicable Standard

[64] The parties agree that the Protective Orders require at their paragraph 27 that BI has the burden to establish on the balance of probabilities that the information it has designated as SEO in its productions is, in fact, SEO information. In doing so, the Court must have regard to the terms of the Protective Orders that permit information to be designated as SEO.

[65] As set out in *Surewex USA Inc. v. Dentec Safety Specialists Inc.*, 2022 FC 1190 (CanLII) at paragraph 45 (“*Surewex*”), the test to be applied in a challenge to a SEO designation is the test set out in the Protective Orders themselves, notwithstanding that the test agreed upon by the parties and set out in the Protective Orders may resemble the test for the granting of a protective order as set out in *AB Hassle v Canada (Minister of National Health and Welfare)* (1998), 1998 CanLII 8942 (FC), 83 CPR (3d) 428 (FCTD), aff’d 2000 CanLII 17121 (FCA), [2000], 5 CPR (4th) 149 (FCA), further elaborated upon with respect to SEO or Confidentiality terms within a proposed protective order in *Angelcare Development Inc. v. Munchkin, Inc.*, 2018 FC 447, *Arkipelago Architecture Inc. v. Enghouse Systems Limited*, 2018 FC 37 (CanLII); *Bard Peripheral Vascular Inc v WL Gore & Associates, Inc.*, 2017 FC 585; *Lundbeck Canada Inc v Canada (Health)*, 2007 FC 412, *Merck & Co Inc v Brantford Chemicals Inc*, 2005 FC 1360, *Depura Partners LLC's v. Desjardins General Insurance Inc.*, 2020 FC 261 (CanLII), at para. 10 and *Rivard Instruments Inc v Ideal Instruments Inc*, 2006 FC 1338 at para. 40.

[66] In this case, as set out in paragraph 3 of the Protective Orders, the operative terms for a SEO designation are set out in paragraph 4(b) of the Protective Orders while the operative terms applicable to an SEO designation challenge are set out in paragraph 27. Paragraph 4(b) read together with paragraph 27 of the Protective Orders requires that BI establish on the balance of probabilities that:

- a) it in good faith believes the Information it marked as SEO information is maintained by it as confidential;
- b) it in good faith considers the Information to be of a particularly sensitive nature, or of a commercial valuable nature to the Defendants; and,
- c) the Information is or contains technical, scientific, sales, marketing, financial, business strategy, competitive intelligence, or other commercially sensitive information or proprietary information not otherwise known or available to the public, whether embodied in physical objects, documents, or the factual knowledge of persons or discussion of same.

[67] The test to be applied is therefore subjective with respect to its first and second components in that BI's good faith belief as to the first and second components to be established, and objective as to its third component with respect to the nature of the information that has been designated SEO.

[68] I note that the SEO designation challenge test set out in the Protective Orders agreed upon by the parties and issued on consent in this case makes no reference to any consideration of

the objective harm that may reasonably result from the disclosure of SEO Information. In this sense, the test applicable to the SEO Information designations in this case differs significantly from the test applied in *Surewex* because, as noted by Justice Go in *Surewex* at paragraph 2, the Protective Order in *Surewex* incorporated the notion of potential harm arising from disclosure and therefore required the Court to consider whether harm would result as part of the challenge. That is not the case here. I must therefore proceed on the basis of the test set out in the Protective Orders that were the result of the parties' agreement and the Court's review prior to their issue as Orders of the Court (*Fluid Energy Group Ltd. v. Mud Master Drilling Fluid Services Ltd.*, 2020 FC 229 (CanLII), at paras. 40 and 48). If BI satisfies the Court through its evidence that the SEO Information falls within the scope of the Protective Orders, then it has met its burden and it falls to the Defendants to lead evidence that the SEO marked information and documents fall outside of what was contemplated by the Protective Orders.

[69] I therefore reject the Defendants' arguments that BI is required to meet the requirements set out in *AB Hassle v Canada (Minister of National Health and Welfare)* (1998), 1998 CanLII 8942 (FC), 83 CPR (3d) 428 (FCTD), aff'd 2000 CanLII 17121 (FCA), [2000], 5 CPR (4th) 149 (FCA) [*AB Hassle*] to maintain its SEO designations. The time to argue whether BI could meet the *AB Hassle* test was when the protective order was being considered for issue, not when a challenge to a marked document is undertaken (*Fluid Energy Group Ltd. v. Mud Master Drilling Fluid Services Ltd.*, 2020 FC 229 (CanLII), at para. 42; *AB Hassle v. Canada (Minister of National Health and Welfare)* (C.A.), 2000 CanLII 17121 (FCA), [2000] 3 FC 360, at paras. 10 and 11). In this case, as the Defendants agreed on the terms of the Protective Orders and consented to their issue, the Defendants must have accepted that BI met the *AB Hassle* test at the

time of the Protective Orders' issue by the Court. They must be held to their bargain absent compelling evidence otherwise. BI does not have to argue or met the *AB Hassle* test on the Defendants' challenge here.

2) The Evidence

[70] BI has led evidence relating to its SEO designations through the affidavit of Haris Hadzimuratovic, referred to above, as well as through the affidavit of Dr. Markus Weymann, Head of Global Patents Human Pharma Biologics, Boehringer Ingelheim International GmbH.

[71] Mr. Hadzimuratovic deposes that each of BI's SEO Productions are internal BI documents that generally fall into two categories: (i) lab notebooks; and (ii) the results from various research and development work undertaken by BI's researchers or for BI. Mr. Hadzimuratovic also explains how and why the information and documents marked as SEO Information is kept and maintained as confidential information by BI.

[72] Dr. Weymann's affidavit speaks to his review of samples of the SEO marked documents included in BI's affidavits of documents. Like Mr. Hadzimuratovic, he describes the documents described in BI's affidavit of documents provided to him for his review and information as generally falling within into two main groups, being BI lab notebook documents and documents that contain results obtained by testing and analysis. For ease of reference throughout his affidavit he refers to the documents together as the BI "R&D Documents" as they all relate to BI's research and development work carried on by BI's employees or on BI's behalf with respect to the investigation, discovery and development of new and better medicines.

[73] In this particular case, he deposes that the R&D Documents in BI's affidavits of documents relate specifically to the research and development work that went into BI's Jardiance product that are particularly sensitive as they set out information regarding the various steps and analyses that BI went through in arriving at its Jardiance product. These documents are generally not disclosed outside of BI. In addition, the R&D Documents show attempted compound formulations and tests that are not relevant to the claims at issue in this proceeding and speak to BI's development work in a larger product development context that is not public, and is confidential. The documents and the information they contain are a roadmap to BI's research and development work and provide insight into the process and approach taken by BI's researches into its broader SGLT-2 program.

[74] Dr. Weymann also deposes that BI's R&D Documents and the information they contain continue to be used confidentially by BI in its research work and is maintained as particularly sensitive information.

[75] Dr. Weymann deposes that the information contained in the BI R&D documents are of a particularly sensitive nature and would also be of significant commercial value to the Defendants in their work as generic pharmaceutical companies who seek to sell and market generic versions of BI's empagliflozin product.

[76] The Court is satisfied that BI has led evidence to establish on a balance of probabilities that:

- a) it in good faith believes the Information it marked as SEO Information is maintained by it as confidential;
- b) it in good faith considers the Information it marked as SEO Information to be of a particularly sensitive nature, or of a commercial valuable nature to the Defendants; and,
- c) the Information is or contains technical, scientific, sales, marketing, financial, business strategy, competitive intelligence, or other commercially sensitive information or proprietary information not otherwise known or available to the public, whether embodied in physical objects, documents, or the factual knowledge of persons or discussion of same.

[77] BI has therefore met its burden of proof to meet the requirements for proper SEO designations as stipulated in paragraph 4(b) and paragraph 27 of the Protective Orders.

[78] The Defendants have not tendered any evidence contrary to BI's evidence with respect to these points. The affidavits they rely upon do not speak to any of the three items BI is required to establish on this motion to satisfy the Court that the information marked as SEO information is marked in accordance with the terms of the issued Protective Orders. Instead, the Defendants argue that BI's evidence beggars belief that a sophisticated litigant such as BI can in good faith consider every document related to years of product development to be "particularly sensitive" or of such commercial value to the Defendants that special protection is required. The

Defendant's arguments on these points are made without evidence sufficient to rebut the positive evidence tended by BI.

[79] The remainder of the Defendants' arguments with respect to this issue delve into the negotiations that led to the issued Protective Orders – without any admissible evidence to support their argument – and address the *AB Hassle* test that BI has already satisfied with the Defendants' consent and which led to the Court's issue of the Protective Orders.

[80] The Defendants have led no evidence to rebut BI's evidence as to the appropriateness of the SEO Information designations as required by the terms of the Protective Orders. Their arguments fall short or miss the mark entirely. Their challenge must fail.

III COSTS DIRECTIONS

[81] The parties have each sought their costs of this motion.

[82] I strongly encourage the parties to confer and attempt to agree on the costs of this motion prior to December 11, 2023. If the parties agree on costs by then, they may deliver a letter on consent to the case management office in Ottawa to my attention that sets out their agreement as to costs and, if the Court considers such costs appropriate, a subsequent Order as to costs consistent with the parties' agreement as to costs will issue.

[83] In the event that the parties do not agree on the costs of this motion, then the Plaintiffs shall have until December 12, 2023, to serve and file their respective costs submissions that do

not exceed three pages, double-spaced, exclusive of schedules, appendices and authorities. The Defendants will then have until December 22, 2023, to serve and file their costs submissions, also limited to three pages, double-spaced, exclusive of schedules, appendices and authorities.

[84] If no agreement as to costs is filed by December 11, 2023, and no costs submissions are served and filed by December 12, 2023, then no costs will be awarded on this motion.

THIS COURT ORDERS that:

1. The Defendants' challenge to documents designated by BI as Solicitors Eyes Only pursuant to clauses 4(b) and 27 the Protective Orders issued in proceedings are dismissed.
2. The Defendants' challenge to the redactions made by BI to certain production documents pursuant to clause 11 of the Protective Orders issued in these proceedings is also dismissed.
3. The Plaintiffs' motion is granted.
4. Costs of this motion are reserved to be determined in accordance with the directions given above.

“Benoit M. Duchesne”
Case Management Judge