
IN RE: TASIGNA PRODUCTS
LIABILITY LITIGATION

SUPERIOR COURT OF NEW JERSEY

LAW DIVISION: BERGEN COUNTY
CASE NO. 635
MASTER DOCKET NO.: BER-L

CIVIL ACTION

ESI DOCUMENT PRODUCTION
PROTOCOL AND ORDER

FILED
JUL 09 2021
RACHELLE L. HARZ
J.B.C.

A. The procedures and protocols outlined herein govern the production of electronically stored information (“ESI”) and paper documents by the Parties during the pendency of this litigation. The production formats for any other materials will be addressed by the parties after a meet and confer.

B. Duty of Cooperation

The parties acknowledge their duty to work together cooperatively throughout the discovery process.

C. Definitions

1. **“Defendant”** means and refers to Novartis Pharmaceuticals Corporation.
2. **“Document”** is defined to be synonymous in meaning and equal in scope to the usage of this term in Rules 4:10-2 and 4:18-1 of the New Jersey Rules of Court. The term “Document” shall include Hard-Copy Documents, Electronic Documents, and ESI as defined herein.
3. **“Electronic Document or Data”** means Documents or Data existing in electronic form at the time of collection, including but not limited to: e-mail or other means of electronic communications, word processing files (e.g., Microsoft Word), computer presentations (e.g., PowerPoint files), spreadsheets (e.g., Excel), and image files (e.g., jpg).

4. “**Electronically stored information**” or “**ESI**,” as used herein has the same meaning as in Rules 4:10-2 and 4:18-1 of the New Jersey Rules of Court.

5. “**Hard-Copy Document**” means Documents existing in paper form at the time of collection.

6. “**Native Format**” means and refers to the format of ESI in which it was generated and/or as used by the producing party in the usual course of its business and in its regularly conducted activities. For example, the native format of some Excel workbooks is a .xls or .xlsx file.

7. “**Metadata**” means: (i) structured, i.e., fielded, information embedded in a native file that describes, *inter alia*, the characteristics, origins, usage, and/or validity of the electronic file; and (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted, or otherwise manipulated by a user of such system.

8. “**Media**” means an object or device, real or virtual, including but not limited to a disc, tape, computer, or other device on which data is or was stored.

9. “**Optical Character Recognition**” or “**OCR**” means a software process of recognizing, and creating a file containing visible text within an image.

10. “**Hash Value**” is a unique numerical identifier that can be assigned to a file, a group of files, or a portion of a file, based on a standard mathematical algorithm applied to the characteristics of the data set.

11. “**Confidentiality Designation**” means the legend affixed to Documents for Confidential Discovery Information. Any Party may designate a document as Confidential Material that the party reasonably believes qualifies as such, by stamping it “Confidential,”

“Subject to Confidentiality Agreement,” or “Subject to Protective Order.” The Party shall affix the stamp in such a manner so as not to obscure the text of the document. For Confidential Material produced in native format, the Producing party will indicate the designation on a slip-sheet corresponding to the native format document.

12. “**Searchable Text**” means the native text extracted from an Electronic Document and any Optical Character Recognition text (“**OCR text**”) generated from a Hard-Copy Document or electronic image.

13. “**Load files**” means electronic files provided with a production set of documents and images used to load that production set into a receiving party’s document review platform, and correlate its data within that platform.

14. “**And**” and “**or**” shall be construed conjunctively or disjunctively as necessary to make their use inclusive rather than exclusive, e.g., “**and**” shall be construed to mean “**and/or**”.

15. “**Include**” and “**Including**” shall be construed to mean “include but not be limited to” and “including, but not limited to,”.

16. Reference to the singular shall also be deemed to refer to the plural, and vice-versa.

D. Preservation

1. Defendant represents that they have issued litigation hold notices to those custodians who reasonably may be expected to have data, and to persons or entities responsible for maintenance of non-custodial data, which data reasonably may be expected to have discoverable information, and have established procedures to ensure that those notices have been received, understood and appropriately acted upon. Defendant utilizes established procedures to preserve data consistent with its obligations. For example, Defendant represents that since approximately 2012, it has used a Microsoft O365 suite, which includes a ‘litigation hold’ feature that is used on both custodial and non-custodial data within the Microsoft O365 suite that is

identified as subject to a litigation hold notice. The litigation hold feature disables a custodian's ability to delete email or OneDriveforBusiness (ODB) data. Therefore, available email data will continue to be preserved while the custodians are on legal hold.

2. This protocol does not expand any Party's common-law or statutory duties to preserve evidence. In the event that a Party identifies backup, disaster recovery or archive media that reasonably may contain unique discoverable data, that Party will disclose the existence of such backup, disaster recovery, or archive media to the other Party. Upon such disclosure, the parties will meet and confer regarding which, if any, of those systems must be preserved.

3. Plaintiffs represent that they will preserve all data under their control that may reasonably be expected to contain discoverable information.

4. All processes and procedures that would result in the elimination, or transfer to a less accessible medium, of any unpreserved data and associated metadata that would otherwise be required to be preserved or produced have been suspended.

E. Document and Data Sources

1. On September 21, 2020, Defendant provided a list identifying and describing custodial and non-custodial data sources which may reasonably be expected to contain discoverable information. Defendant agrees to supplement this list if it identifies additional ESI data sources which may reasonably be expected to contain discoverable information. The inclusion of a source on this list does not constitute an agreement that data from the source is appropriately within the bounds of discovery in this case.

2. On September 21, 2020, Defendant provided a list identifying the names, titles and roles of custodians in primary functional roles involving Tassigna who Defendant reasonably expects to have discoverable information. Defendant will supplement this list if it becomes aware of additional custodians in primary functional roles involving Tassigna who Defendant reasonably

expects to have discoverable information. The Parties agree to confer regarding the identification of custodians and the selection of custodians for inclusion in document productions in this case. Nothing in this provision shall be construed to impair or impede Plaintiffs' right to conduct discovery to identify additional, relevant custodians.

3. Plaintiffs reserve the right to request, at any time prior to the close of discovery, inclusion of additional custodians or non-custodial data sources. If the Defendant objects to the inclusion of such non-custodial or custodial sources, the Parties will meet and confer to resolve the matter; if the Parties cannot reach resolution, the Court or its designee will determine the matter.

4. Documents and ESI from identified custodial and non-custodial data sources will be preserved pending identification of data to be produced into this litigation.

5. If there is a dispute concerning the scope of a party's preservation or collection efforts, the parties shall meet and confer and fully explain their reason for believing additional efforts are, or are not, relevant and unduly burdensome pursuant to Rules 4:10-2(a) and 4:10-2(f)(2).

6. *Not reasonably accessible ("NRA") data sources.* A producing party shall not have an obligation initially to search, or to produce from, sources of electronically stored information that they have shown are not reasonably accessible because of undue burden or cost in accordance with Rule 4:10-2(f)(2), and no such obligation will arise unless and until a showing of good cause is made by the requesting party that such searches and production are necessary considering the limitations of Rule 4:10-2(g). A producing party retains the right to argue that certain sources of electronically stored information are not reasonably accessible because of undue burden or cost and further retains the right to seek cost shifting.

7. Absent a showing of good cause or written agreement of the parties, there is no need to preserve or collect ESI from the following sources, which are deemed to be NRA. There may be additional categories of ESI not listed below that are NRA.

- a. ESI deleted in the normal course of business before the time a preservation obligation in this action came into effect;
- b. “deleted,” “slack,” “fragmented,” or “unallocated” data on hard drives only accessible by forensics;
- c. Random access memory (RAM), temporary files created by an operating system or application without human intervention, or other ephemeral data;
- d. On-line access data such as temporary internet files, history, cache, cookies, etc.;
- e. Data in metadata fields that are frequently updated automatically, such as last-opened dates or last-printed dates;
- f. Server, system, network, or software application logs; and
- g. Specified structural files not material to individual file contents (e.g., .ccs, .xsl, .sml, .dtd, etc.).

8. Absent a party’s specific written notice for good cause, no party shall be required to modify or suspend procedures, including rotation of backup media, used in the normal course of business to back up data and systems for disaster recovery purposes. Nothing in this provision obviates a party’s duty to implement a litigation hold.

F. Defendant’s Identification and Classification of Documents and ESI

1. The parties agree to the use of search terms in connection with Defendant’s production of documents and ESI.

2. The parties agree to meet and confer regarding the selection of search terms to be used to identify potentially relevant documents and ESI and a search term protocol. The parties reserve all rights with regard to the terms and scope of such a protocol.

G. Plaintiffs' Identification and Classification of Documents and ESI

1. To the extent Plaintiffs used or maintained any of the following ESI sources two (2) years prior to Tassigna treatment or any time since treatment, Plaintiffs shall search the following sources for responsive ESI to the extent such sources are reasonably accessible to the Plaintiffs: (i) any personal (i.e. non-work) email accounts used by plaintiffs; (ii) any personal electronic devices used by plaintiffs (e.g., desktop or laptop computers, tablets, mobile phones, digital cameras); (iii) any other personal hardware storage devices used by plaintiffs (e.g., external hard drives, memory cards, USB or thumb drives, CDs/DVDs); (iv) any website where a plaintiffs made online postings (e.g., on a blog, message board, etc.); (v) any cloud storage used by plaintiffs (e.g., DropBox, Microsoft Office365 Account, Google Drive, iCloud, Amazon Drive, etc.).

2. To the extent Plaintiffs used or maintained any social media (e.g., Facebook, Instagram, LinkedIn, Twitter, MySpace, YouTube, Pinterest, or other online collaboration tools such as Slack, Google+, Windows Live, or Yahoo! Groups), Plaintiffs will produce relevant ESI through the use of the "Download Your Information" tool or other similar tool provided by the relevant social media platform. In the event a social media platform contains relevant ESI but does not have an analogous tool to the "Download Your Information" tool, Plaintiffs will notify Defendant and the parties will meet and confer regarding production. The parties agree to meet and confer regarding potential alternative production formats in the event that a party believes that ESI that has been produced using a "Download Your Information" tool does not sufficiently capture relevant data.

3. In the event that Plaintiffs are aware of additional ESI sources not included in ¶¶ 1 and 2 above that Plaintiffs reasonably believe may contain discoverable data, such as work emails, Plaintiffs will identify such sources to Defendant. The parties agree to meet and confer regarding the potential collection and production from such sources.

4. The parties agree to meet and confer regarding the process by which potentially relevant documents and ESI are identified from sources identified in ¶¶ 1 and 2, including use of and selection of search terms.

5. Plaintiffs shall produce Documents and ESI in native file format, PDF, or such other reasonably useable format that retains the relevant characteristics of the original Document. For email families in Plaintiffs' productions, the parent-child relationships (the association between emails and attachments) should be preserved. Any Document that requires redaction shall be produced in image format, *e.g.*, TIFF or PDF. All of Plaintiffs' production Documents shall be uniquely named and sequentially numbered with Bates Stamps.

6. To the extent Plaintiffs produce a Document other than in native format, and Defendant requests metadata or other information, the Parties shall reasonably confer about an alternative production format for such Document, including the necessity for such alternative production format.

H. Prior Document Productions

Documents that were previously processed and produced in another litigation, including the *Lauris* and *McWilliams* cases, or in response to governmental or regulatory inquiries or investigations, may be produced in the same format as they were produced in that particular litigation, inquiry, or investigation, regardless of whether the format complies with the other specifications described herein. The parties agree to meet and confer with respect to the

preservation, collection, validation, production, and any potential re-production of the documents produced in any such prior document production.

I. Documents with Insufficient Text

To the extent a party identifies document sources that are reasonably believed to be responsive and for which text-based search technologies are fundamentally ineffective, such sources must be reviewed without culling by search terms, predictive coding, or other technologies that rely primarily on text.

J. Additional or Alternate Methodologies for Documents from Certain Custodians and Non-Custodial Data Sources.

Upon request, the Parties will meet and confer to address the need for and implementation of additional or alternate methodologies for identifying possibly responsive documents from custodians and non-custodial data sources that may warrant such treatment.

K. Mobile and Handheld Device Documents and Data.

Defendant states that mobile devices will not be included as a default data source due to proportionality considerations and the expectation that unique responsive data, if any, will be limited. In the event that potentially relevant for production, unique data is identified on a mobile device, the parties will meet and confer.

L. Production Format and Processing Specifications

1. Non-redacted spreadsheet (e.g., Microsoft Excel) files shall be produced as native files with TIFF placeholder images. Spreadsheet files requiring redaction, including Microsoft Excel files, will be redacted within the native file, where technically feasible, and the redacted native file will be produced as provided herein. Where redactions in the native file are not technically feasible, spreadsheets will be redacted and produced as TIFFs.

2. All word processing (e.g., Microsoft Word), presentation (e.g., Microsoft PowerPoint), image (e.g., .jpg, .gif), and PDF files shall be produced as native files with TIFF placeholder images where reasonably possible, unless redactions are required, in which case such files shall be produced as TIFFs. All media files, such as audio and video files and digital photographs, shall be produced as native files with TIFF placeholder images.

3. Emails shall be produced as TIFFs.

4. The Parties will meet and confer on the production format of less-commonly used file types, such as CAD, GIS data, materials and prototypes testing, etc.

5. Any party seeking to use, in any proceeding in this litigation, files produced in native format shall do so subject to the following:

- a. If the native file has been converted to TIFF-image or hardcopy, the slip sheet containing the original production number and any confidentiality designation shall be appended to the first page of the document prior to use.
- b. If the native file will be used in its native format, the Party seeking to use the native file shall associate therewith the slip sheet containing the original production number and any confidentiality designation.

6. Any Party using native format files during course of this litigation, for instance as an exhibit at a deposition or at trial, as an exhibit to a motion, or providing documents to an expert, is responsible for ensuring that the slip sheet associated with each native file is attached to the native file prior to its use, and that any confidentiality designation of the file is appropriately addressed.

7. Use of a file in native format or use of a TIFF image or hardcopy document representing the original native format file, shall constitute a representation that the file being used is an accurate and unaltered depiction of the original native format file.

8. All ESI shall be produced with applicable metadata as specified in Attachment A, and, where possible, searchable text extracted from the ESI. Redacted ESI, other than spreadsheet files that are produced as redacted native files, will be produced as TIFFs with applicable metadata as set out in Attachment A and OCR'ed searchable text. Hard-copy documents will be scanned and produced as TIFFs, with applicable metadata as set out in Attachment A, and OCR'ed searchable text.

9. Embedded Objects. OLE embedded objects (embedded MS Office files, etc.) shall be extracted as separate files and treated as attachments to the parent document. If reasonably possible, images embedded in emails shall not be produced separately.

10. Load Files. Productions will include image load files in Opticon or IPRO format as well as Concordance format data (.dat) files with the metadata fields identified in Attachment A for all included documents. All metadata will be produced in UTF-8 format.

11. Foreign Language Documents. Hard-copy documents and ESI that are produced containing languages other than English, in whole or in part, shall be produced in the original language(s). Existing translations created in the normal course of business shall be produced.

12. Text Files. A single text file shall be provided for each document. The text file name shall be the same as the Bates number of the first page of the document with the document extension ".txt" suffixed. Files names shall not have any special characters or embedded spaces. Electronic text must be extracted directly from the native electronic file unless the document requires redaction and is not a spreadsheet redacted and produced in TIF format, is an image file,

or is any other native electronic file that does not contain text to extract (e.g., non-searchable PDFs). In these instances, and in the case of imaged hard-copy documents, a text file shall be created using OCR and shall be produced in lieu of extracted text. Text shall be provided in UTF-8 format. Extracted text shall include all comments, revisions, tracked changes, speaker's notes and text from documents with comments or tracked changes, and hidden worksheets, slides, columns and rows.

13. OCR. OCR software should be set to the highest quality setting during processing. Documents containing foreign language text shall be OCR'ed using the appropriate settings for that language, e.g., OCR of German documents will use settings that properly capture umlauts. Settings such as "auto-skewing" and "auto-rotation" should be turned on during the OCR process.

14. Text Extracted from Emails. Text extracted from emails shall include all header information that would be visible if the email was viewed in Outlook including: (1) the individuals to whom the communication was directed ("To"), (2) the author of the email communication ("From"), (3) who was copied and blind copied on such email ("CC" and "BCC"), (4) the subject line of the email ("RE" or "Subject"), (5) the date and time of the email, and (6) the names of any attachments.

15. TIFFs. All TIFFs produced by any party in this matter will be single page Group IV TIFF format, 300 dpi quality or better. Image file names will be identical to the corresponding bates numbered images, with a ".tif" file extension. All images of documents that contain comments, deletions and revision marks (including the identity of the person making the deletion or revision and the date and time thereof), speaker notes, or other user-entered data that the source application can display to the user will be processed such that all that data is visible in the image. The producing party will brand all TIFF images in the lower right-hand corner with its

corresponding bates number, using a consistent font type and size. The Bates number must not obscure any part of the underlying image. If the placement in the lower right-hand corner will result in obscuring the underlying image, the Bates number should be placed as near to that position as possible while preserving the underlying image.

16. TIFFs of Redacted ESI. TIFFs of redacted ESI shall include all non-redacted elements and formatting which are visible in any view of the document in its native application, and each redacted area must bear a label containing the reason for the redaction.

17. Bates Numbers. All bates numbers will consist of an Alpha Prefix, followed immediately by an 8-digit numeric: e.g., TPROD#####. There must be no spaces in the Bates number. Any numbers with fewer than 8 digits will be front padded with zeros to reach the required 8 digits.

18. Date Fields Time Zone. All documents shall be processed so as to show fielded dates and times in UTC.

19. Exception Files. The Parties will use reasonable efforts and standard industry practices to address Documents that present imaging or form production problems (including encrypted and/or protected files identified during the processing of ESI) (“Exception Files”). The Parties will meet and confer regarding procedures that will be used to identify, access, and process Exception Files. If the Parties cannot reach agreement on the handling of Exception Files through the meet and confer process, the matter may be submitted to the Court for determination.

20. Native File Image Placeholders. A Bates-stamped placeholder TIFF, bearing the legend “This document has been produced in native format” shall be provided for ESI produced in native format; these placeholders will be Bates numbered in the same way as any other TIFF,

and the Bates number of that single page shall be used as the BegBates and EndBates of the associated document.

21. Databases, Structured, Aggregated or Application Data. The Parties will meet and confer to address the production and production format of potentially responsive data for production contained in a database or other structured or aggregated data source or otherwise maintained by an application. The Parties will cooperate in the exchange of information concerning such databases and data sources to facilitate discussions on productions and production format. If the Parties cannot reach agreement, the matter will be decided by the Court or its designee.

22. De-NISTing. Electronic files will be De-NISTed, removing commercially available operating system and application file information contained on the current NIST file list.

23. Scanning of Hard-Copy Documents. In scanning paper documents, documents are to be produced as they are kept. For documents found in folders or other containers with labels, tabs, or other identifying information, such labels and tabs shall be scanned where practicable. Pages with Post-It notes shall be scanned both with and without the Post-it, with the image of the page with the Post-it preceding the image of the page without the Post-It. The parties will use reasonable efforts to unitize documents (*i.e.*, distinct documents should not be merged into a single record, and a single document should not be split into multiple records), and maintain document relationships, *i.e.*, attachment status. The parties may unitize their documents using either physical unitization (*i.e.*, based on physical binding or organizational elements present with the original paper documents like staples, clips and binder inserts) or logical unitization (*i.e.*, a manual review of the paper to determine what logically constitutes a document like page numbers or headers).

The parties will meet and confer to resolve any related issues. Original document orientation (*i.e.*, portrait v. landscape) should be maintained.

24. Proprietary Software. To the extent that produced ESI cannot be rendered or reviewed without the use of proprietary software, the parties shall meet and confer to minimize any expense or burden associated with the production of such documents in an acceptable format, including issues as may arise with respect to obtaining access to any such software and operating manuals.

25. Confidentiality Treatment. The parties have entered into a stipulated Confidentiality Order in this matter.

- a. The confidentiality designation for any item will be provided with the created data for that item, in the field entitled "Confidentiality Treatment." For items with no confidentiality requirements, the field will be left blank.
- b. The producing party will brand any confidentiality endorsements in a corner of any TIFF images representing the produced item. Those endorsements must be in a consistent font type and size, and must not obscure any part of the underlying image or Bates number.

26. Redactions. To the extent that a responsive document contains (a) privileged content, (b) non-responsive Confidential information regarding non-responsive products, or (c) information required to be redacted by applicable law, the Producing Party may produce that document in a redacted form. Any redactions and the reasons therefore shall be clearly indicated on the face of the document. For redacted items that were originally ESI, all non-redacted metadata fields set out in Attachment A will be provided and will include all non-redacted data. Redacted documents shall be identified as such in the load file provided with the production. A document's

status as redacted does not relieve the producing party from providing all of the non-redacted metadata required herein.

27. De-duplication. Defendants shall make reasonable efforts to de-duplicate ESI. ESI produced by Defendants shall be globally de-duplicated across all collected custodial and non-custodial sources. Documents are considered exact duplicates if a document family or stand-alone file has a matching MD5 or SHA-1 hash value as compared against the same document type (i.e., family or stand-alone file). Defendants shall disclose the method used to create hash values for emails and email families. The Parties shall meet and confer as to the appropriate metadata fields after such disclosure. The names of all custodians and non-custodial sources included in productions in this matter who were in possession of a document prior to deduplication shall be populated in a metadata field.

28. Email Threading. No email may be withheld because it is included in whole or in part in a more inclusive email, although parties may use email threading for their own internal review and other internal processes.

29. Color. The Parties will accommodate requests made in good faith for the production of a color image of specific documents originally produced in black-and-white TIFF format where reasonably necessary to decipher the complete meaning, context, and/or content of the documents. Such responsive ESI shall be produced in a manner that preserves, to the maximum extent possible, the integrity of multi-page groups of documents.

30. Encrypted or Password-Protected ESI. For any ESI that is produced in encrypted format or is password-protected, the producing party, where reasonably possible to do so, will provide the propounding party a means to gain access to those native files (for example, by supplying passwords), if known by the party.

31. Parent-Child Relationships. Parent-child relationships (the association between an attachment and its parent document or between embedded documents and their parent) shall be preserved.

32. Family Groups. A document and all other documents in its attachment range, emails with attachments and files with extracted embedded OLE documents all constitute family groups. If any member of a family group is produced, the parent shall be produced along with all other responsive family members; slipsheets shall be produced for all unproduced privileged or non-responsive family members.

33. Production Media. The producing party will use the appropriate electronic media (CD, DVD or hard drive) or secure electronic transfer for its ESI production, and, if physical media is being provided, will cooperate in good faith to use the highest-capacity available media to minimize associated overhead. The producing party will label the physical media with the producing party, production date, media volume name, and document number range. Any replacement Production Media will cross-reference the original Production Media, clearly identify that it is a replacement and cross-reference the Bates Number range that is being replaced.

34. Write Protection and Preservation. All computer media that is capable of write protection should be write-protected before production.

M. Alternate Formats.

Notwithstanding the Parties' stipulations herein, upon reasonable request made by the Receiving Party, the Parties shall confer regarding the production in an alternate format of a document previously produced in accordance with this order.

N. Privilege Log.

1. Within thirty (30) days of the final production, a producing party shall provide a log of the documents withheld or redacted for privilege, with a log populated with the following

extracted metadata fields: Custodian, From, To, CC, BCC, Subject, File Name, Family Date, Date Created or Sent, Date Last Modified, Basis of Withholding/Redaction. In-house attorney names shall be designated with an asterisk; outside counsel attorney names must be designated with a double asterisk. The following documents presumptively need not be included on a privilege log:

(a) Written or oral communications between a party and its counsel related to the conduct of litigation after the commencement of such litigation; or (b) Work product created by outside counsel, or by an agent of outside counsel (other than a party) related to the conduct of litigation after the commencement of such litigation. In advance of a privilege log being produced by NPC, reasonable requests by Plaintiffs to provide the privilege log information required by this section for specific documents will not be rejected.

2. After receipt of privilege log information, any Party may dispute a claim of privilege or protection; however, prior to any submission to the Court for an in camera review, the Party disputing a claim of privilege or protection shall provide in writing the identification of the documents for which it questions the claim of privilege or protection and the reasons (including legal support) for its assertion that the documents are not privileged or protected. Within twenty-one (21) days, the Party seeking to support the claim of privilege or protection shall provide a written response supporting the claim of privilege or protection (including legal support). The Parties will then meet and confer in good faith as to the claims of privilege or protection. If agreement cannot be met, any party may thereafter submit the material under seal to the Court for a determination as to privilege or protection. If a party believes the circumstances require different timing or procedure, they shall meet and confer on alternatives to resolving any disputes and if unable to agree may present the issue to the Court.

O. Limitations and Non-Waiver.

This protocol provides a general framework for the production of ESI and paper

documents on a going forward basis. The Parties and their attorneys do not intend by this protocol to waive their rights to the attorney-client or work-product privileges.

P. General Provisions.

1. Any practice or procedure set forth herein may be varied by agreement of the Parties, and first will be confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of electronic data or other covered discovery materials.

2. Nothing in this Order shall be interpreted to imply that documents produced by parties in this case are properly discoverable, relevant, or admissible in this (or any other) lawsuit.

3. Should any Party subsequently determine in good faith that it cannot proceed as required by this order or that the order requires modification, the Parties will meet and confer to resolve any dispute before seeking Court intervention. Any Party may, after meeting and conferring, submit any disagreement to the Court for resolution.

Q. Data Protection Laws

The parties agree to confer regarding the format for production of any information that a party reasonably believes in good faith to be subject to federal, state or foreign data protection laws or other privacy obligations, which may constitute highly sensitive materials requiring special protection, review, processing, and procedures. Examples of such data protection laws may include but are not limited to The Gramm-Leach-Bliley Act, 15 U.S.C. § 6801 et seq. (financial information); The Health Insurance Portability and Accountability Act and the regulations thereunder, 45 CFR Part 160 and Subparts A and E of Part 164 (medical information); Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information);

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and repealing Directive 95/46/EC (General Data Protection Regulation) (L119/1) (EU personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the Spanish Data Protection Act 1/1999; the Belgian Law of December 8, 1992 on Privacy Protection in relation to the Processing of Personal Data (Belgium personal information); The Federal Law on Protection of Personal Data held by Private Parties (published July 5, 2010) (Mexico personal information); and The Act on the Protection of Personal Information (Law No. 57 of 2003) (APPI) (Japan personal information); the Federal Data Protection Act of 1992 (Swiss personal information); and Personal Information Protection and Electronic Documents Act (PIPEDA), S.C. 2000, c. 5 (Canada personal information).

IT IS SO STIPULATED, through Counsel of Record.

Dated: June __, 2021	<hr/> <i>/s/ Richard Elias</i> Richard Elias <i>Attorney for Plaintiffs</i>
Dated: June __, 2021	<hr/> <i>/s/ Melanie H. Muhlstock</i> Melanie H. Muhlstock <i>Attorney for Plaintiffs</i>
Dated: June __, 2021	<hr/> <i>/s/ James G. Onder</i> James G. Onder <i>Attorney for Plaintiffs</i>
Dated: June __, 2021	<hr/> <i>/s/ Kelly Jones Howell</i> Kelly Jones Howell <i>Attorney for Defendant Novartis Pharmaceuticals Corporation</i>

Attachment A

Field Name	Description	Email	Loose Files/ Att.
StartBates	The Bates number for the first page of the document.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
EndBates	The Bates number for the last page of the document.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Start Attachment	The first Bates number of the first attachment to an email.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
End Attachment	The ending Bates number of the last page of the last attachment to an Email.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
ParentBates	First bates number of the parent document for each attachment record.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
From	The reported sender of an Email message.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
To	The reported recipient(s) of an Email message contained in the "To" field.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
cc	The reported recipient(s) of an Email message contained in the "CC" field.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BCC	The reported recipient(s) of an Email message contained in the "BCC" field.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
SentDate	The date on which an Email was sent by the user's Email software (if available) in UTC time.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Field Name	Description	Email	Loose Files/ Att.
SentTime	The time at which an Email was sent by the user's Email software (if not included in SentDate) in UTC time.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EmailSubject	The Subject Line of an Email.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Attachment Count	The number of attachments to an Email	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FileName	The file name.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FilePath	Original filepath of the location where the item resided at the time of preservation. This should include any container, folders/directories, and, in the case of standalone files or non-email attachments, file name.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
KIND	Descriptor for the kind of document. Sample values include: Calendar Entry; Contact; Database; Document; Drawing; Email; Image; Multimedia; No Data; Other Document; Presentation; Spreadsheet; System File; Unrecognized.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
FileExt	The file extension.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Author	The author of the file as extracted from the file metadata.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CreatedDate	The date the file was created as extracted from the file metadata.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CreatedTime	The time the file was created as extracted from the file metadata.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
LastModDate	The date on which the file was last modified as extracted from the file metadata.	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Field Name	Description	Email	Loose Files/ Att.
LastModTime	The time at which the file was last modified as extracted from the file metadata.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
MD5Hash	The MD-5 hash value of the file.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Custodian	Custodian or source associated with the produced record.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
OTHERCUSTODIANS	Names of any other custodians whose copy of the document was not produced as a duplicate in format last name, first names with each name delimited by semi-colons	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
TEXTPATH	The path to the extracted text for the file (if needed).	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
NATIVE PATH	The path to the native document on the production media (where native file is produced).	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
REDACTED	"Redacted" (or other, similar indication) for redacted documents and indication of the reason for the redaction (e.g., "AC," "WP," "PII" or similar); otherwise, blank.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CONVERSATIONID	Email thread Identifier	Yes	No
ATTACHMENTS	Names of each individual email attachment, separated by semi-colons	Email only	Email Only
TITLE	Internal document property	No	Yes

Field Name	Description	Email	Loose Files/ Att.
OTHERFILEPAT HS	Original filepath of the locations where unproduced copies resided at the time of preservation. This should include any container, folders/directories, and, in the case of standalone files or non-email attachments, file name.	Yes	Yes
ProdVol	Production volume	Yes	Yes
Confidentiality	Confidentiality level per the protective order	Yes	Yes
LASTMODIFIE DBY	Internal Office document property; last person who modified a document	No	Yes