IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	C. A. No. 14-cv-268-SLR

PROTOCOL REGARDING DISCOVERY OF
ELECTRONICALLY STORED INFORMATION AND HARD COPY DOCUMENTS

After conferring on these matters, Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") and Defendant Watson Laboratories, Inc. ("Watson") each agree to the following protocol ("Protocol") regarding the discovery of electronically stored information ("ESI") and hard copy documents in the above-captioned case. To the extent this Protocol does not address certain issues, those issues remain open for resolution in a separate protocol, either negotiated by the parties or ordered by the Court. Nothing in this Protocol alters a party's rights, obligations and responsibilities under the Federal Rules of Civil Procedure. The parties believe that, at this juncture, this Protocol will provide for effective and efficient discovery of electronically stored information and hard copy documents in accordance with the Federal Rules of Civil Procedure. Pursuant to the Federal Rules of Civil Procedure, each party will bear the cost for the collection, searching, review and production of their own reasonably accessible Hard Copy Documents and ESI hereunder, absent a showing of good cause to apportion costs.

I. DEFINITIONS.

The following definitions will apply in this Protocol:

A. Bates Number means a unique alphanumeric identifier associated with

every physical sheet of paper, electronically stored TIFF image, or other tangible thing, consisting of (1) an alphabetic portion identifying the producing party and/or other characteristics of the production; and (2) a numeric portion incremented according to a scheme defined at the producing party's discretion to ensure that the alphanumeric identifier for each physical sheet of paper, electronically stored TIFF image, or other tangible thing is unique.

B. **Document** means any thing subject to production or inspection under Federal Rule of Civil Procedure 34(a), including (1) any document or ESI—including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations—stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form; or (2) any tangible thing.

C. **General ESI** includes (1) electronically stored email messages; (2) word processing documents (created with, for example, Microsoft Word and WordPerfect); (3) files formatted for display in a web browser, for example, files with an .htm, .html, .php, or .cfm extension; (4) Adobe Acrobat files; (5) ASCII text files, for example, files with a .txt file extension; and (6) presentation documents and embedded files (created with, for example, Microsoft PowerPoint).

D. **Hard Copy Document** means a Document kept in physical form, as opposed to electronic form, in the usual course of business.

E. **Native Format** means the associated file format defined by the original application with which an electronic file was created. For example, the Native Format associated with a Microsoft Word 2007 file is .docx and the Native Format associated

with an Adobe Acrobat file is .pdf.

F. **Spreadsheet** means an electronic file that displays multiple cells that together make up a grid consisting of rows and columns, at least some of the cells containing either alphanumeric text or numeric values or a formula, including, but not limited to, files created with Microsoft Excel.

II. ESI PRODUCTION PROTOCOL AND SCHEDULE.

In an effort to identify ESI that may be responsive to proper and unobjectionable document requests and to avoid disputes over the scope of electronic discovery, the parties adopt the following protocol and schedule to determine appropriate sources and search terms for locating potentially responsive ESI. This protocol and schedule is applicable only to ESI and does not apply to a party's obligation to collect and produce Hard Copy Documents responsive to document requests.

A. The manner of production of ESI is to be governed by Federal Rule of Civil Procedure 34(b)(2)(E).

B. On **October 16, 2014** the parties:

(1) Will exchange the names, job titles, and positions of the ten individuals most likely to possess or control potentially relevant ESI information (custodians);

(2) Will exchange lists of other, non-duplicative sources of potentially relevant ESI not limited to the identified custodians (e.g., shared networks, servers, databases); and

(3) Will exchange proposed lists of internal search terms that will, in the proposing party's good faith belief, encompass all responsive information, and

to which the other party may, within ten calendar days and in good faith, add up to ten additional search terms. Absent a showing of good cause, a requesting party may not request more than 10 additional terms to be used in connection with the electronic search. The parties shall use and as necessary propose focused terms, rather than over-broad terms (e.g., product and company names). If a party has good cause to believe that any additional terms proposed by the other party are over-broad, the parties shall meet and confer before the proposed term or terms in question are employed in a search. If the parties cannot reach an agreement regarding any proposed search terms, either party may seek relief from the Court.

C. The parties are to use good faith efforts to produce all responsive identified ESI as promptly as practicable. If a party has good cause to believe that the other party's ESI sources and search terms have failed to identify substantially all responsive ESI, the party may request a meet and confer to discuss its concerns and may seek further amendments to the producing party's ESI sources and search terms. The parties shall meet and confer to discuss further amendment of ESI sources and search terms. If the parties cannot reach agreement on further amendment of ESI sources and search terms, the party seeking to amend ESI sources and/or search terms may seek relief from the Court. Until the Court resolves any such relief, the producing party is under no obligation to amend its ESI sources and/or search terms.

D. The production of any requested responsive and non-privileged ESI shall take place through a rolling production process. If upon reviewing each other's document productions either party requires documents from additional custodians, the

requesting party shall promptly notify the other party. A party being requested to produce additional information is not required to undertake any steps to comply with said request until such time as there is an agreement between the parties or, as necessary, an Order from the Court.

III. PRODUCTION PROTOCOLS FOR ESI.

Documents that originated as ESI will be produced, as far as reasonably possible, in the following formats:

A. General ESI. General ESI will be produced as 300 D.P.I. Group IV compression single-page TIFF images ("Production Images") with associated text files and a Bates Number, as described in §§ III.E-III.L below. If a party has a reasonable belief that the Production Images and associated text files for particular General ESI, identified by Bates Number, do not include information available from the Native Format version of that General ESI, that party may request production of the Native Format version of that General ESI. For example, presentations and other documents may feature color, animation, or other information that does not appear in the Production Images as it would appear when viewed natively. The parties agree to negotiate in good faith regarding production of the requested General ESI, such as in instances where production according to the protocols expressly set forth herein are impracticable, with the goal of avoiding any undue burden on the producing party while ensuring a reasonably usable production for the receiving party.

B. Spreadsheets. A party may request that a spreadsheet be produced in its Native electronic format. The request for a spreadsheet in Native electronic format shall be made in good faith after reviewing the non-native version and providing a reasonable

basis why Native electronic format is required. Should the producing party object to production of a spreadsheet in native form, the parties should meet and confer to settle the dispute and raise the matter with the Court if the dispute cannot be resolved. Spreadsheets should contain the Bates number and Confidentiality designation of the file in the file title.

C. Other Categories of ESI. For ESI that does not qualify as General ESI or Spreadsheets, the parties will meet and confer as to the proper form of production to ensure the efficient and effective review of such materials. As necessary or appropriate, the parties agree to negotiate in good faith regarding search queries to be used to generate reports from proprietary and/or custom databases such that those reports are produced in a reasonably usable form. When practical, the ESI should contain the Bates number and Confidentiality designation of the file in the file title.

D. Images. Documents may be produced as black and white single page TIFF images at 300 D.P.I. Group IV compression. If the need arises to view a particular document in color, a party may request production of color JPEG images for that document. All redactions must be clearly marked on the produced image with "Redacted" or similar marking.

E. Unique IDs. Each Production Image will have a unique file name and will be named with the Bates Number assigned to it.

F. Parent-Child Relationships. Parent-child relationships (the association between an attachment and its parent Document) must be preserved in such a way that a Document and any attachments to that Document are produced in the same production set and are identifiable as parent and child.

G. Database Load Files/Cross-Reference Files. For each document produced in Native Format, absent special circumstances (such as the production of source code separately from other production materials), the parties will make best efforts to include in the production a placeholder image bearing the Bates number of the native file, and the DAT file shall include for each document the production path, and required metadata as set forth below in paragraph I.

H. Documents that originated as General ESI or Spreadsheets will be produced with (1) a Concordance delimited file (DAT) and (2) an Opticon delimited file (LOG or OPT). **Metadata Fields**. The following metadata fields will be provided, if available, for each electronic Document converted to TIFF format images:

DocBeg/ProdBeg	Auto-generated number (i.e., Production Number) of First Page of Document
DocEnd/ProdEnd	Auto-generated number (i.e., Production Number) of Last Page of Document
DocType	Type of Document (e.g., "Email", "Attachment", or "Edoc")
Custodian	Name for the mail user or owner of the document collection
BegAtt	DocBeg of first document in the Attachment Range
EndAtt	DocBeg of last document in the Attachment Range
Title	Subject of E-Mail message or from properties of application file
SentTime	Time e-mail message sent
Date	Date e-mail message sent
Author	Author from properties of application file
From	E-mail Sender Name
To	E-Mail Recipients (TO field)
Copied	E-Mail Courtesy Copy Recipients
BCC	Email Blind Courtesy Copy Recipients
CreatedDate	Date the doc was created
CreatedTime	Time the doc was created
ModifiedDate	Date the doc was last modified
ModifiedTime	Time the doc was last modified
NativePath	Path to the native file in the production
FileExtension*	Filename extension of e-mail attachment or application file
TextPath*	Path to the multi-page TXT files in the delivery
FileTitle	Title of file

Delimiters:

Field Qualifier (quote):	(254)
Field Delimiter (comma):	(020)
Newline Delimiter:	(174)
Multi-entry Delimiter:	(059)
Date Format:	MM/DD/YYYY
Null Fields:	Left empty
Field Names in First Line:	Yes

I. Metadata Format. Extracted Text and OCR should be produced as follows: Accompanying extracted text files shall be multi-page and should be named with the corresponding Doc Beg followed by the extension ".TXT." Text shall be UTF-8 compliant for foreign language collections. For documents containing redactions, Optical Character Recognition ("OCR") text will be substituted for extracted text files. OCR Text shall be provided in multi-page searchable ASCII text format and shall be named with the unique DocBeg of the corresponding TIFF document followed by the extension ".TXT". Single-page TIFF images should appear in a folder in a numbered format. OCR files should be contained in a separate folder titled "OCR." Redacted foreign language documents need not be accompanied by OCR text.

J. **Non-English General ESI**. Textual information associated with General ESI will be produced at least in the language in which it is kept in the usual course of business. This protocol does not address matters relating to the translation of documents that may be produced in discovery.

K. **Text Must Be Generated from General ESI**. Textual information associated with General ESI must be produced by extracting text from the General ESI, when available, not by performing optical character recognition ("OCR") on images generated by scanning paper copies generated from electronically stored information. The parties, however, should produce OCR for any General ESI that does not contain

extractable information (e.g., non-searchable PDFs).

L. Non-Production of Certain ESI. At the present time, by the exchange of this protocol, the parties have informed each other that the following categories of documents are not reasonably accessible because of undue burden or cost. As a result, it is the parties' intention not to collect, process, review, and/or produce such documents at this time. These forms of ESI that are not reasonably accessible include:

1. Voicemail messages;
2. Random access memory;
3. Instant messages, text messages, and chats;
4. Sound recordings, including, without limitation, .mp3 and .wav files;
5. Information stored in unallocated space in file systems on magnetic media;
6. Information from BlackBerry or other handheld devices that is duplicative of data stored on e-mail servers;
7. Deleted, fragmented, or other data accessible only by forensics;
8. On-line access data (e.g., temporary internet files, history, cache, cookies);
9. Dynamic fields of databases or log files that are not stored or retained in the usual course of business;
10. Optical or other sequential tape backup systems either (1) optimized for disaster recovery as opposed to partial or incremental recovery or (2) for which hardware and software

recovery tools are unavailable to the party from its own internal resources; and

11. Information created or copied during the routine, good-faith performance of processes for the deployment, maintenance, retirement, and disposition of computer equipment by the party.

The parties agree that in the event that either party determines that production of any form of electronically stored information listed above is reasonably necessary, they will meet and confer regarding whether that discovery should be had, with the right to seek Court relief if agreement cannot be reached.

M. No Obligation to Retain Post-Filing Backups. The parties agree that neither party has any obligation to retain or produce information from any backup tapes and other backup media generated after the initiation of this case ("Post-Filing Backups"). Both parties may continue the routine, good faith operation of their electronic information systems relating to Post-Filing Backups, including, but not limited to, recycling of backup tapes and rewriting of magnetic media. Nothing in this provision shall be construed to excuse a party's obligation to retain information in accordance with the Federal Rules of Civil Procedure and applicable case law.

N. No Obligation to Convert Third Party Productions. The parties agree that any document production received from a third party shall be produced in the format in which it was received.

O. Deduplication. The parties agree to employ industry-standard deduplication procedures—within custodian for e-mail ESI and across custodians for non-e-mail ESI including, without limitation, MD5, SHA-1 and/or SHA-180 hash code

comparison in order to avoid the production of documents that are complete duplicates of other documents already produced or selected for production.

P. On-Site Inspection of Electronic Media. On-site inspection of electronic media is not permitted absent a demonstration by the requesting party of specific need and good cause.

Q. Format of Production. The parties agree that any documents produced will also be made available via secure file transfer if requested by the receiving party.

IV. PRODUCTION FORMATS FOR HARD COPY DOCUMENTS.

Documents that originated as Hard Copy Documents will be produced in the following format:

A. Images. Documents shall be produced as single-page black and white TIFF images at 300 D.P.I. Group IV compression. If the need arises to view a particular document in color, a party may request production of color JPEG images for that document. In the event that information is redacted, regardless of format, all redactions must be clearly marked on the produced image.

B. Unique IDs. Each image will have a unique file name and will be named with the Bates Number assigned to it.

C. Unitization. In scanning Hard Copy Documents, distinct documents will not be merged into a single record, and single documents will not be split into multiple records (i.e., paper documents will be logically unitized). The parties will commit to re-unitize improperly unitized documents.

D. Parent-Child Relationships. Parent-child relationships (the association between an attachment and its parent Hard Copy Document) must be preserved in such a

way that a Hard Copy Document and any attachments to that Hard Copy Document are produced in the same production set and are identifiable.

E. Preservation of Filing and Other Information. Images of all file labels, file headings, and file folders associated with any Hard Copy Document, the production of which is required under applicable discovery rules and case law, will be produced with that Hard Copy Document.

F. Database Load Files/Cross-Reference Files. Documents that originated as Hard Copy Documents will be produced with (1) a Concordance delimited file, and (2) an Opticon delimited file.

G. Objective Coding Fields. The following objective coding fields will be provided, if available, for Documents originating as Hard Copy Documents:

1. Beginning Bates Number
2. Ending Bates Number
3. Beginning Attachment Number
4. Ending Attachment Number
5. Custodian or File Location
6. Textpath (if OCR is going to be produced)

H. Objective Coding Format. Objective coding information must be provided in a text file formatted according to industry-standard formats, including, without limitation, ASCII text, or Unicode, if applicable. Objective coding must follow the standard Concordance data structure. The parties shall work together in good faith to resolve any issues regarding data format.

I. OCR Files. Hard copy documents shall be scanned using OCR

technology and searchable ASCII text files shall be produced. In addition, the content of these text files must be associated with the particular TIFF format images reflecting the content of that Hard Copy Document through a database load file/cross-reference file as described in § IV.F above and included as a field in the record in the database load file/cross-reference file associated with those particular TIFF format images.

J. Non-English Hard Copy Documents. Hard Copy Documents will be produced in the language in which they are kept in the usual course of business. This protocol does not address matters relating to the translation of documents that may be produced in discovery.

K. Format of Production. The parties agree that any documents produced will also be made available via secure file transfer if requested by the receiving party and technically feasible. If the parties agree to produce documents only through secure file transfer, documents will be considered "produced" as of the date and time they are uploaded to the server and made accessible to the requesting party.

V. PRIVILEGED DOCUMENTS OR INFORMATION

A. There is no duty to disclose privileged documents or information.

B. On **January 30, 2015**, the parties shall exchange privilege logs identifying any documents or information withheld as privileged or otherwise protected and the basis for any claim of privilege or other protection in a manner that, without revealing information itself privileged or otherwise protected, will enable the other parties to assess the applicability of the privilege or other protection. The parties will confer to attempt to resolve any disputes relating to protection on a good faith basis prior to seeking the Court's assistance. A party may move the Court for an order compelling the production

of any withheld documents or information identified on any other party's privilege log.

C. The parties are not required to include on their privilege logs any protected documents that (a) came into existence on or after **February 20, 2012**, with the limited exceptions that (i) Watson will log protected documents directly pertaining to Watson's decision to seek a carve out for the use of colchicine to treat and prevent gout flares from its proposed labeling, which came into existence on or after **January 30, 2014**, but before **May 9, 2014**, and which do not pertain to communications between Watson and its outside counsel, and (ii) Takeda will log protected documents directly pertaining to Watson's decision to seek a carve out for the use of colchicine to treat and prevent gout flares from its proposed labeling, which came into existence on or after **January 30, 2014**, but before **May 9, 2014**, and which do not pertain to communications between Takeda and its outside counsel; (b) constitute communications between the parties and their respective outside counsel for this action; or (c) are redacted as non-responsive. Where a protected email chain is at issue, the listing on the log will (a) indicate that the document is an email chain, (b) describe the last communication in the email chain, and (c) identify all correspondents on the most recent email in the chain.

D. The inadvertent production of privileged or work product protected information is not a waiver of any applicable privilege in this suit. The parties agree that in the event that privileged information is inadvertently produced or inadvertently left undesignated with a confidentiality designation, the receiving party will treat the information in accordance with Section IV of the Discovery Confidentiality Order.

E. ESI identified as "CONFIDENTIAL" or HIGHLY CONFIDENTIAL—OUTSIDE ATTORNEY'S EYES ONLY" shall be handled in accordance with the

provisions of the Stipulated Discovery Confidentiality Order entered in the case.

VI. SCOPE OF AGREEMENT

The parties agree that this Protocol shall govern the conduct of ESI and Hard Copy Document production with respect to the issues addressed in this Protocol. The parties may, by written agreement, amend or otherwise modify this Protocol. Nothing in this Protocol is intended to, or does, waive any objections to discovery or admissibility, or any other privileges or immunities or, except as specifically provided herein, impose obligations different than those contained in the Federal Rules of Civil Procedure and/or the Federal Rules of Evidence. The parties recognize that additional issues or unforeseen circumstances may arise in the course of discovery, and nothing in this Protocol is intended to, or does, restrict the ability of any party to request additional information or seek additional relief from the Court. The parties each retain the right to seek exceptions, amendments or modifications to this Protocol from the Court.

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SO ORDERED THIS ____ day of _____, 2014.

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United States District Court Judge