

# **EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

THE PROCTER & GAMBLE COMPANY	)	
and HOFFMANN-LA ROCHE INC.,	)	
	)	Civil Action No. 08-627-JJF
	)	Civil Action No. 09-143-JJF
Plaintiffs,	)	
	)	<u>CONSOLIDATED</u>
v.	)	
	)	Hon. Judge Joseph J. Farnan, Jr.
TEVA PHARMACEUTICALS USA, INC.,	)	
	)	Magistrate Judge Leonard P. Stark
and	)	
	)	
APOTEX INC. and APOTEX CORP.	)	
	)	
Defendants.	)	
_____	)	

**DEFENDANTS' SECOND SET OF REQUESTS FOR THE  
PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFF  
THE PROCTER & GAMBLE COMPANY (NOS. 62 - 91)**

In accordance with Rules 26 and 34 of the Federal Rules of Civil Procedure, defendants Apotex, Inc. and Apotex Corp. request that plaintiff The Procter & Gamble Company respond to the following production requests and produce the requested documents and things within thirty (30) days.

**DEFINITIONS AND INSTRUCTIONS**

A. The form of the responses to Defendants' discovery requests must comply with Rules 26 through 37 of the Federal Rules of Civil Procedure.

B. Defendants' discovery requests will be deemed to seek responses as of the date they are served. Any additional responsive information, documents, or things that become known to Plaintiff up to and including the time of trial must be furnished to Defendants within a reasonable time after becoming known. Moreover, if Plaintiff acquires any information,

documents, or things that require an answer to be enlarged, diminished, or otherwise modified, such information, documents, or things must be supplied to Defendants within a reasonable time after they are acquired.

C. The phrase “the ’938 patent” means United States Patent No. 7,192,938, entitled “Method of Treatment Using Bisphosphonic Acid,” which issued on March 20, 2007.

D. The phrase “the ’513 patent” means United States Patent No. 6,165,513, entitled “Film-coated Tablet For Improved Upper Gastrointestinal Tract Safety,” which issued on December 26, 2000.

E. The phrase “patents in suit” means the ’938 patent or the ’513 patent or both.

F. The term “invention” includes every alleged invention or discovery disclosed or claimed in the patents in suit. By using the term “invention,” Defendants do not admit that either of the patents in suit is valid or discloses or claims a patentable invention.

G. The terms “infringe” and “infringement” includes literal infringement, infringement under the doctrine of equivalents, direct infringement, contributory infringement, and induced infringement.

H. The term “Roche” means plaintiff Hoffmann-La Roche Inc. (“Roche”), any predecessor or successor company or individual, and any corporation or other business entity (whether or not a separate legal entity) subsidiary to, parent of, or affiliated with Roche, as well as all present and former principals, partners, directors, owners, officers, members, employees, agents, representatives, consultants, and attorneys of Roche, or any affiliated corporation or business entity controlled by Roche.

I. The term “P&G” means plaintiff The Procter & Gamble Company (“P&G”), any predecessor or successor company or individual, and any corporation or other business entity

(whether or not a separate legal entity) subsidiary to, parent of, or affiliated with P&G, as well as all present and former principals, partners, directors, owners, officers, members, employees, agents, representatives, consultants, and attorneys of P&G, or any affiliated corporation or business entity controlled by P&G.

J. The term "FDA" means the United States Food and Drug Administration.

K. The term "PTO" means the United States Patent and Trademark Office.

L. The term "NDA 20-835" means P&G's New Drug Application No. 20-835.

M. The term "NDA 21-455" means Roche's New Drug Application No. 21-455.

N. The term "risedronate" means a drug product or active pharmaceutical ingredient containing risedronic acid, or any of its salts or hydrates.

O. The term "Once-a-Month Actonel®" means P&G's 150 mg Actonel® product, where Actonel® refers to P&G's risedronate product.

P. The term "ibandronate" means a drug product or active pharmaceutical ingredient containing ibandronic acid, or any of its salts or hydrates.

Q. The term "Roche's ibandronate product" means the ibandronate products marketed and sold by Roche, including, but not limited to, pharmaceutical products marketed and sold under the trade name "Boniva®."

R. The term "bisphosphonate" means a drug product or active pharmaceutical ingredient containing bisphosphonic acid, or any its salts or hydrates. The term "bisphosphonic acid" means compounds characterized by two phosphonate groups linked by phosphoether bonds to a central (geminal) carbon atom. ('938 patent, col. 3, lines 26-28.) Such bisphosphonates include, but are not limited to, alendronate, clodronate, tiludronate, etidronate, ibandronate, neridronate, olpadronate, risedronate, pamidronate, and zolendronate.

S. The term "Defendant's ANDA product" means the product for which Apotex Corp. is seeking approval in its Abbreviated New Drug Application No. 90-877.

T. The term "document" has the comprehensive meaning, in the broadest sense available pursuant to Rule 34(a) of the Federal Rules of Civil Procedure, and includes each handwritten, typed, printed or otherwise recorded material, whether an original or a copy of an original bearing any notation or marking not appearing on the original (including, but not limited to, notes and underscoring), in the possession, custody, or control of Roche, including, but not limited to, letters, cables, wires, messages, telexes, telecopies, memoranda, inter-office and intra-corporate communications, reports, notes, minutes, bulletins, circulars, pamphlets, instructions, work assignments, notebooks, drafts, work sheets, appraisals, advertisements, catalogs, brochures, flyers, invoices, purchase orders, acknowledgements, price lists, proposals, quotations, solicitations, and bids; drawings, diagrams, blueprints, plans, sketches, charts, graphs, tracings, photographs, audio tapes, videotapes, and motion pictures; printouts, recordings, tapes, disks, roms, proms, eproms, data compilations, and other information from computers or other data storage and retrieval systems; trademark registrations, copyright registrations, and registration applications; patents and patent applications; assignments, deeds, contracts, agreements, licenses, and other official documents and legal instruments; newspapers, magazines, books, periodicals, and other published material of any kind; annual reports, reports to shareholders or owners, and minutes or reports of meetings of owners or directors or executive boards or committees; summaries of negotiations or meetings; quality control, operating, service, repair, or maintenance manuals; technical specifications or requirements; advertising and promotional material as well as sales literature; labels and packaging; press releases and new product releases; engineering notebooks and data; ledgers, journals, bills, checks, receipts,

vouchers, statements, orders, records, and files; address books, appointment books, telephone logs, calendars, diaries, and desk pads; affidavits, declarations, and transcripts of testimony; and other writings and recordings (as defined in Fed. R. Evid. 1001) of whatever nature; including copies and mechanical or photocopy reproductions of any or all of the foregoing items. Where such copies or reproductions contain any marking not appearing on the original or are altered from the original, then such copies or reproductions will be considered to be separate original documents.

U. The term “thing” means any physical specimen or tangible item including, but not limited to, samples, prototypes, mock-ups, test equipment, production equipment, tools, dies, molds, models, three-dimensional illustrations of physical or chemical phenomena and montages of physical items.

V. The term “concerning” means comprising, containing, constituting, embodying, evidencing, discussing, reflecting, relating to, referring to, or identifying.

W. The term “communication” means the transfer or transmittal of information (in the form of facts, ideas, inquiries, or otherwise) whether oral or written.

X. The terms “possession,” “custody,” and “control” are used in a comprehensive sense and refer to possession, custody, or control by any one or a combination of the following persons or organizations:

1. Plaintiff;
2. Any corporation or other entity controlled by or affiliated with Plaintiff or controlling Plaintiff as its wholly owned subsidiary;
3. Any principal, officer, employee, agent, representative, or consultant of or for Plaintiff or any such controlled or affiliated corporation or entity; and
4. Counsel for Plaintiff or any such controlled or affiliated corporation or entity.

Y. The term “person” means any natural person.

Z. The term “organization” means any legal or business entity, including, but not limited to, public and/or private corporations, partnerships, and proprietorships, as well as other legal business entities, e.g., agencies, associations, forms, and trusts, whether domestic or foreign.

AA. The terms “and” or “or” must both be read in the conjunctive and in the disjunctive wherever they appear, and neither of these words will be interpreted to limit the scope of a discovery request.

BB. The use of a verb in any tense will be construed as the use of the verb in all other tenses, and the singular form will be deemed to include the plural and vice-versa.

CC. The term “identify” in the case of a document means to state:

1. The document’s title and date, if any, as well as a brief description of its subject matter;
2. The type or nature of the document (e.g., letter, memorandum, telegram, chart, laboratory report, etc.) and the number of pages in it;
3. The identity of any person who prepared the document (and, if different, the identity of any person who signed the document);
4. The date the document was drafted;
5. The identity of any person who received a copy of the document (whether an addressee or otherwise);
6. The present whereabouts of the document and the identity of its custodian; and
7. All other means of identifying the document with sufficient particularity to support a request for production under Rule 34 of the Federal Rules of Civil Procedure.

DD. The term “identify” in the case of a thing means to state:

1. A brief description of the thing, including any product numbers, part numbers, model numbers, catalog numbers, style numbers, code numbers, brand names, trade names, trademarks, commercial or governmental designations, and any other identifying markings, features, or characteristics;
2. The present whereabouts of the thing;
3. The identity of the person having possession, custody, or control of the thing; and
4. All other means of identifying the thing with sufficient particularity to support a request for production under Rule 34 of the Federal Rules of Civil Procedure.

EE. The term “identify” in the case of a person means to state:

1. The person’s home and business addresses (present or last known);
2. The person’s full name; and
3. The time period and nature of each of his or her present and prior employment positions or affiliations with Plaintiff, if any.

FF. The term “identify” in the case of an organization means to state:

1. The organization’s full name;
2. The organization’s type (e.g., public or private corporation, partnership, etc.);
3. The last known street and post office addresses of its principal place of business;
4. The date(s) and state(s) or country(ies) of incorporation;
5. The identity of each of its principals, officers, directors, partners, or members; and
6. The date of dissolution, if applicable.

GG. Plaintiff shall produce electronically stored information in the form or forms to be agreed upon by the parties. Paper documents shall be produced as images in order to reduce copying charges thus controlling costs. The images will be in black-and-white, single page, 300



DPI, Group IV Tiff images, with load files, each single page TIFF named for its bates number, and load files containing page breaks and source/custodial information, which can be loaded into popular litigation software packages. These load files should support Summation and include a Summation dii file. Additionally, P&G's IND and NDA, if available electronically, should be produced in the format in which it was originally submitted to the FDA with all the functionality maintained. Plaintiff will accommodate reasonable requests for production of specific images in color.

HH. If Plaintiff objects to producing and withhold from production any information, documents, or things requested herein on grounds of attorney-client privilege, work-product immunity, or otherwise, Defendants request that Plaintiff provide within thirty (30) days of service of these discovery requests a privilege log identifying the specific grounds on which the objection rests and the particular request(s) objected to, and identifying any withheld documents, things, or portions thereof as follows:

1. Its date of creation;
2. The identity of all persons who prepared and/or signed the document or thing, including the persons' positions or affiliations with Plaintiff at the time the document or thing was created;
3. The general nature of the document or thing (i.e., whether it is a letter, chart, pamphlet, memorandum, etc.);
4. A summary of its contents, or the general subject matter of the document or thing;
5. Its present location and the identity of its current custodian;
6. A listing of all persons, including, but not limited to, the addressee, to whom copies of the document or thing have been disclosed, including the date and means of disclosure, and each person's positions or affiliation with Plaintiff at the time the document or thing was created, and specifically whether each person was an attorney at the time the document or thing was created; and

7. The nature of the privilege or other rule of law relied on to withhold the document or thing and the facts supporting Plaintiff's assertion thereof.

II. If any documents or things requested to be produced herein have been lost, discarded, destroyed, or are otherwise unavailable for any reason, they should be identified as completely as possible, by stating without limitation: the pertinent information requested in the preceding paragraph, the date of disposal, the manner of disposal, the reason for disposal, any person who or organization that has possession, custody, or control of a partial or incomplete copy of such document, and the identity of all persons who participated in the destruction or discarding or who have knowledge of the circumstances surrounding the destruction or discarding of the document or thing.

JJ. Defendants request that any purportedly privileged document containing nonprivileged matter be produced with the purportedly privileged portion excised.

KK. In responding to Defendants' discovery requests, if Plaintiff claims any ambiguity in interpreting either a request, a definition, or an instruction, Plaintiff must not use that ambiguity claim as a basis for refusing to respond, but must instead set forth as part of its response to the request the language deemed to be ambiguous and the interpretation that it has chosen to use in responding to the request.

#### **REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS**

##### **Request No. 62.**

The final agreement or agreements concerning the sale of P&G's pharmaceuticals business to Warner Chilcott.

**Request No. 63.**

All documents and things concerning the transfer, grant, conveyance, assignment, or license of any interest in or right to any of the patents in suit in connection with the sale of P&G's pharmaceuticals business to Warner Chilcott.

**Request No. 64.**

All documents and things concerning any communications between or among P&G, Roche and/or Warner Chilcott concerning the transfer, grant, conveyance, assignment, or license of any interest in or right to the '938 patent in connection with the sale of P&G's pharmaceutical business to Warner Chilcott.

**Request No. 65.**

All document and things concerning any representations and/or warranties made with respect to the patents in suit in connection with the sale of P&G's pharmaceuticals business to Warner Chilcott.

**Request No. 66.**

All documents and thing concerning any valuation of the P&G's Actonel® product in connection with the sale of P&G's pharmaceutical business to Warner Chilcott.

**Request No. 67.**

All documents and things concerning the decision not to bring an action against Defendants Apotex Inc. and Apotex Corp. for infringement of the '513 patent.

**Request No. 68.**

A copy of any opinions of counsel referring or relating to the '513 patent.

**Request No. 69.**

A copy of all communications to or from any expert, consultant, or third-party concerning the '513 patent.

**Request No. 70.**

Any patent, publication or other document identified by any third party who has ever questioned or disputed the validity and/or the enforceability of the '513 patent or any foreign counterpart patent or application.

**Request No. 71.**

All communications between P&G and Roche regarding film-coated oral dosage forms covered by the claims of the '513 patent.

**Request No. 72.**

A copy of any file for the '513 patent maintained by or for P&G.

**Request No. 73.**

All documents and things produced by P&G in any patent infringement action involving the '513 patent.

**Request No. 74.**

All documents and things concerning any settlement, judgment, dismissal and/or consent judgment in any patent infringement action involving the '513 patent.

**Request No. 75.**

All documents and things concerning the decision to seek patent coverage for the subject matter of any of the claims in the '513 patent.

**Request No. 76.**

All documents and things concerning the meaning of any term, phrase, limitation, or element in any claim in the '513 patent.

**Request No. 77.**

All documents and things concerning any secondary indicia of nonobviousness with respect to the '513 patent including, but not limited to, commercial success, commercial acquiescence, copying, long-felt need, failure of others and profession/industry approval.

**Request No. 78.**

A copy of any and all prior art submitted by the applicants or cited by the Patent Examiner during prosecution of the application for the '513 patent in the PTO including, but not limited to, patents, printed publications, public uses, sales, offers for sale and public knowledge known by or considered by the named inventors and any other person involved in the prosecution of the application that led to the '513 patent.

**Request No. 79.**

All documents and things concerning the best mode known to the respective inventors for practicing the inventions claimed in the '513 patent.

**Request No. 80.**

All documents and things concerning the dates of conception and reduction to practice of any invention claimed in the '513 patent.

**Request No. 81.**

All documents and things concerning the research, development, formulation, testing, implementation, or operation of any invention claimed in the '513 patent including, but not limited to, research notebooks, laboratory notebooks, correspondence, analyses, studies, experiments, reports, sketches, interview reports or summaries, clinical data, description of tests or studies, and results or conclusions reached from such tests or studies.

**Request No. 82.**

All documents and things concerning any data, tests, tables, formulations, examples, compositions, or pharmaceutical preparations disclosed in the '513 patent.

**Request No. 83.**

All documents comparing or contrasting any claim in the '513 patent with any prior art including, but not limited to, any prior art submitted to the PTO during the prosecution of the application that led to the issuance of the '513 patent.

**Request No. 84.**

All documents and things concerning the inventorship of any of the claims of the '513 patent, any related patent or any related patent application or foreign counterpart, including but not limited to all documents and things which refer or relate to the contribution(s) of any individual(s) to such claims and any decision regarding the identification of such individual(s) as inventor(s).

**Request No. 85.**

All documents and things referring or relating to the use of the film-coated oral dosage form claimed in the '513 patent in connection with the formulation of any drug product including, but not limited, the identification of all drug products formulated according to the claims of the '513 patent.

**Request No. 86.**

All documents and things concerning all advertising, marketing and promotional materials for any P&G film-coated oral dosage form covered by the claims of the '513 patent including, without limitation, journal advertisements and advertisements in the mass media.

**Request No. 87.**

All documents and things concerning any prior art that teaches away from the claimed invention of the '513 patent.

**Request No. 88.**

All documents and things referring or relating to the United States market for any film-coated oral dosage form covered by any claim of the '513 patent, including but not limited to market potential, market size, market shares, market segments, and current and anticipated trends affecting demand for any claimed film-coated oral dosage form.

**Request No. 89.**

All documents and things concerning any research and/or experimentation conducted in connection with the development of the invention from which the '513 patent issued, whether or not disclosed to the PTO.

**Request No. 90.**

All documents and things concerning projections, histories, market share analyses, reports, price studies, business plans, strategic plans, marketing plans, advertising plans, annual budgets, promotion plans, sales force levels, advertising expenditures, marketing expenditures, promotional expenditures and economic studies concerning the promotion, marketing and sale of any film-coated oral dosage form covered by any claim of the '513 patent.

**Request No. 91.**

All document and things concerning projections, market share analysis, and/or forecasting of future sales of Actonel® provided in connection with negotiations for the sale of P&G's pharmaceuticals business to Warner Chilcott.

Dated: November 25, 2009

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**CERTIFICATE OF SERVICE**

I, Richard W. Riley, hereby certify that on November 25, 2009, a true and correct copy of the foregoing DEFENDANTS' SECOND SET OF REQUESTS FOR THE PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFF THE PROCTER AND GAMBLE COMPANY (NOS. 62 - 91) was caused to be served on the attorneys of record at the following addresses and in the manner indicated:

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*/s/ Richard W. Riley*  
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