

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074

MINORITY (202) 225-5051

<http://oversight.house.gov>

October 3, 2017

Mr. Brenton L. Saunders
Chairman, President, and Chief Executive Officer
Allergan plc
400 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Saunders:

On September 8, 2017, your company announced the transfer of six patents related to its Restasis drug to the Saint Regis Mohawk tribe.¹ The unconventional maneuver has received considerable criticism from the generic competitors challenging the drug's patents under the process Congress created to enable timelier review of such challenges.² Allergan defended the transfer as a "sophisticated opportunity to strengthen the defense" of Restasis' patents.³ The sovereign status of Native American tribes adds time and complexity to contesting the status of the patents in question, because tribes may be immune from the legal claims generic drug makers use to challenge patents and bring less costly drugs to market more quickly.⁴

The Food and Drug Administration approved Restasis as a chronic dry eye treatment in 2003, at which time one of the original patents on the drug's active

¹ Press Release, Allergan, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS Patents (Sept. 8, 2017) *available at* www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr.

² Katie Thomas, *How to Protect a Drug Patent? Give it to a Native American Tribe*, NY TIMES (Sept. 8, 2017), <https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html>; *see* Rachel Sachs, *Be Very, Very Concerned About What Allergan Just Did*, Petrie-Flom Center (Sept. 9 2017), blogs.harvard.edu/billofhealth/2017/09/09/be-very-very-concerned-about-what-allergan-just-did/.

³ Press Release, Allergan, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS Patents (Sept. 8, 2017) *available at* www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr.

⁴ *See* Cynthia Koons & Susan Decker, *Casinos Aren't Enough as Native Tribe Makes Deal on Drug Patents*, BLOOMBERG (Sept. 9, 2017), <https://www.bloomberg.com/news/articles/2017-09-09/casinos-aren-t-enough-as-native-tribe-makes-deal-on-drug-patents>; *see also* Ed Silverman, *Allergan's Deal with the Mohawks Raises Troubling Questions about the Future of Generics*, STAT (Sept. 11 2017), www.statnews.com/pharmalot/2017/09/11/allergan-mohawks-generics/.

ingredient was set to expire in 2014.⁵ That same year, Allergan filed additional patents extending its protections to 2024.⁶ As Allergan's second best-selling drug, Restasis generated nearly \$1.5 billion in revenues for the company last year.⁷

The implications of Allergan's patent transfer raise questions for Congress as the exchange may impair competition across the pharmaceutical industry and ultimately dissuade companies from pursuing less-costly generic alternatives to brand drugs. To assist the Committee in evaluating your company's transfer of Restasis's patents, please provide the following documents and information to the Committee:

1. All agreements and communications between officials at Allergan and the Saint Regis Mohawk tribe referring or relating to the Restasis patents, including but not limited to legal expenses.
2. All analyses conducted in preparation for or relating to any agreements regarding the Restasis patents, including but not limited to all analyses relating to past or future trends or projections for market share.
3. All documents and communications referring or relating to the amount of money received by your company from sales of Restasis through federal health care programs, including state programs that receive federal funding.
4. All documents presented to the Board of Directors concerning any agreements regarding the Restasis patents.
5. All documents and communications referring or relating to considerations for a similar arrangement and transaction for other products.

Provide the requested documents and information as soon as possible, but no later than 5:00 p.m. on October 17, 2017. An attachment to this letter provides additional instructions for responding to the Committee's request.

⁵ See U.S. FOOD & DRUG ADMIN., NO. 021023, DRUG APPROVAL PACKAGE FOR RESTASIS CYCLOSPORINE OPHTHALMIC EMULSION FOR ALLERGAN INC. (Oct. 10, 2003), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-023_Restasis.cfm; *see also* U.S. Patent No. 5,474,979 (filed Dec. 12, 1995).

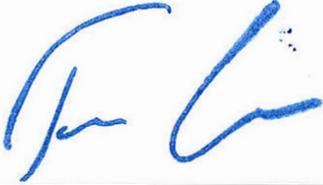
⁶ *Id.*

⁷ Koons & Decker, *supra* note 4.

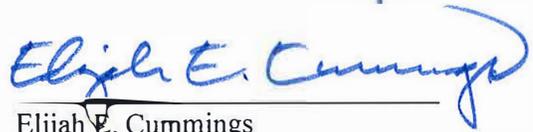
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If you have any questions about this request, please contact Sarah Vance with the Chairman's staff at (202) 225-5074 and William Cunningham with the Ranking Member's staff at (202) 225-5051. Thank you for your prompt attention to this matter.

Sincerely,



Trey Gowdy



Elijah E. Cummings



Dennis A. Ross



Peter Welch

Enclosure

Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.
2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.
3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.
4. Documents produced in electronic format should also be organized, identified, and indexed electronically.
5. Electronic document productions should be prepared according to the following standards:
 - (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - (b) Document numbers in the load file should match document Bates numbers and TIF file names.
 - (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - (d) All electronic documents produced to the Committee should include the following fields of metadata specific to each document:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH,
PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE,
SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM,
CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE,
DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,
INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION,
BEGATTACH.
6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.
8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.
9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.
10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.
11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.
13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.
14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.
15. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.
16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.
17. All documents shall be Bates-stamped sequentially and produced sequentially.
18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.
3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.
4. The terms “person” or “persons” mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.
6. The term “referring or relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.
7. The term “employee” means agent, borrowed employee, casual employee, consultant, contractor, de facto employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee, subcontractor, or any other type of service provider.

**COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
115TH CONGRESS**

NOTICE OF APPEARANCE OF COUNSEL

Counsel submitting: _____

Bar number: _____ **State/District of admission:** _____

Attorney for: _____

Address: _____

Telephone: (_____) _____ - _____

Pursuant to Rule 16 of the Committee Rules, notice is hereby given of the entry of the undersigned as counsel for _____ in (select one):

All matters before the Committee

The following matters (describe the scope of representation):

All further notice and copies of papers and other material relevant to this action should be directed to and served upon:

Attorney's name: _____

Attorney's email address: _____

Firm name (where applicable): _____

Complete Mailing Address: _____

I agree to notify the Committee within 1 business day of any change in representation.

Signature of Attorney

Date