

# **Defendants'**

# **Exhibit 7**



**GlaxoSmithKline**  
709 Swedeland Road  
P.O. Box 1539  
King of Prussia, PA  
19406-0939  
Tel. 610 270 4800  
Fax. 610 270 7777  
www.gsk.com

November 9, 2007

**VIA HAND DELIVERY & E-MAIL**

Brenda Dolan  
Departmental FOIA Officer  
United States Department of Commerce  
Office of Management and Organization  
1401 Constitution Ave., N.W.  
Washington, D.C. 20230-0001

Robert Fawcett  
USPTO FOIA Officer  
United States Patent and Trademark Office  
Madison Building East  
600 Dulany Street  
Alexandria, VA 22314

**Re: Freedom of Information Act Request -- All Materials Relating to  
Certain Proposed and Final Patent Rules**

Dear Officers Dolan and Fawcett:

We respectfully submit the following three-part request to your attention:

A. Under the Freedom of Information Act, 5 U.S.C. § 552, we are requesting copies of all documents that the U.S. Department of Commerce or its component agency, the U.S. Patent and Trademark Office ("USPTO"), **considered** when formulating the proposed rules at 72 Fed. Reg. 48 (Jan. 3, 2006) and 72 Fed. Reg. 61 (Jan. 3, 2006), and the final rules at 72 Fed. Reg. 46,716 (Aug. 21, 2007) (hereafter collectively "PTO Rules"). This FOIA request includes, but is not limited to, all documents concerning the following:

1. the USPTO or U.S. Department of Commerce proposals or decision to limit continuation applications;
2. the USPTO or U.S. Department of Commerce proposals or decision to require a petition and showing for continuation applications;

Robert Fawcett  
November 9, 2007  
Page 2

3. the USPTO or U.S. Department of Commerce proposals or decision to limit the number of claims in a patent application;
4. the USPTO or U.S. Department of Commerce proposals or decision to incorporate an examination support document requirement;
5. the USPTO or U.S. Department of Commerce proposals or decision to limit the number of requests for continued examination;
6. the USPTO or U.S. Department of Commerce proposals or decision to require a petition and showing for requests for continued examination;
7. the USPTO or U.S. Department of Commerce analysis on the extent or limits of its rulemaking authority under the U.S. patent statutes;
8. all changes made to the proposed rules before issuance of the final rules;
9. all alternatives considered for the proposed or final rules, regardless of whether the alternatives were rejected or adopted;
10. any mathematical or policy models used to generate data on or to quantify the patent application process and any explanation of how such models were developed and how they operate;
11. any mathematical or policy models used to generate predictions about patent applications in the system under either the proposed or final rules and any explanation of how such models were developed and how they operate;
12. communications with Congress or any members of Congress in connection with the PTO Rules;
13. communications with any member of the general public, including the media, commentators, professors (including academics of any sort), or businesses, in connection with the PTO Rules;
14. communications with the Office of Management and Budget or any other Executive Branch agency of any kind in connection with the PTO Rules;

Robert Fawcett  
November 9, 2007  
Page 3

15. the impact that the proposed or final rules would have on particular industries, including the pharmaceutical and biotechnology industries;
16. any potential or future rulemakings, or any other initiatives,<sup>1</sup> related to the PTO Rules;
17. the function of the Manual of Patent Examining Procedure (“MPEP”) under the PTO Rules, and consideration of the burdens that MPEP compliance will impose on prospective patent applicants; and
18. information considered for formal inclusion in the administrative record designated for the PTO Rules but ultimately not included in the certified index of such materials.

**B.** Additionally, under the Freedom of Information Act, 5 U.S.C. § 552, please provide us with copies of all documents that the USPTO or the U.S. Department of Commerce was **requested to consider but declined, for any reason, to consider** in formulating the proposed rules at 72 Fed. Reg. 48 and 72 Fed. Reg. 61 and the final rules at 72 Fed. Reg. 46,716. This FOIA request includes, but is not limited to, all sub-categories of documents listed above in part A.1-18.

**C.** We are also requesting, under the Freedom of Information Act, 5 U.S.C. § 552, copies of all documents that the USPTO or the U.S. Department of Commerce considered when formulating any and all **guidance documents** released by the USPTO to the public regarding the final rules at 72 Fed. Reg. 46,716. This FOIA request includes, but is not limited to, all sub-categories of documents listed above in part A.1-18 above, if applicable.

Documents should be separately identified as being responsive to part A., part B., or part C. above, and where fairly possible, also be identified by sub-categories 1-18.

This Freedom of Information Act request (and specifically its short-hand use of the term “documents”) includes, and is not limited to, any memoranda, reports, papers, notes, summaries, case law, emails, voicemails, other communications, presentations, audio/videotapes, or briefings. This request includes any documents or materials in the possession of the U.S. Department of Commerce, USPTO, or both. “And” and “or” as used herein shall be construed both conjunctively and disjunctively in order to bring within the scope of this request any document that would otherwise not be brought within its scope.

---

<sup>1</sup> Brigid Quinn, speaking on behalf of the USPTO, recently stated that the proposed rules “are part of a package of initiatives” in consideration by the USPTO. The Associated Press, *Va. Court Blocks New Patent Rules: Court Grants GlaxoSmithKline’s Request for Temporary Injunction Delaying New Patent Rules*, Oct. 31, 2007. This FOIA request includes any documents related to these initiatives.

Robert Fawcett  
November 9, 2007  
Page 4

We recognize that the U.S. Department of Commerce's FOIA regulations suggest that FOIA requests should be made to the USPTO alone.<sup>2</sup> An abundance of caution counsels us, however, to put this FOIA request before both the U.S. Department of Commerce and USPTO, so that responsive records for both agencies are searched. *See, e.g.*, 37 C.F.R. pt. 102 app. n.1 (requiring that certain USPTO systems of records be maintained by the Department of Commerce and thus are subject to Department of Commerce instead of USPTO regulations). Moreover, the U.S. Department of Commerce has a statutorily defined role in major USPTO policymaking initiatives, which the PTO Rules appear to constitute, given their unprecedented magnitude and scope. *See* 35 U.S.C. § 2(a) ("The United States Patent and Trademark Office, **subject to the policy direction of the Secretary of Commerce** -- 1) shall be responsible for the granting and issuing of patents. . . .") (emphasis added). Hence, the PTO Rules are likely not exclusively a USPTO initiative.

To be clear, we seek all documents described in parts A., B., and C. above, whether generated by USPTO on its own initiative or generated jointly or under the "policy direction of the Secretary of Commerce," and regardless of whether such documents are in the possession of USPTO, the U.S. Department of Commerce, or both. Any response to this FOIA request from the USPTO or the U.S. Department of Commerce should indicate whether there are responsive documents in the exclusive possession of the USPTO or the U.S. Department of Commerce and separately identify any such documents.

If there are any fees for searching or copying the records, please supply the records without informing me of the cost, if the fees do not exceed \$10,000, which we agree to pay in advance. For any fees or expenses above this cost threshold, please contact me with a cost estimate before you fill the request beyond that cost threshold. Please, however, do not delay the assembly or the release of documents responsive to this request which fall under the cost threshold, pending obtaining our agreement to exceed the cost threshold when disclosing other responsive materials.

If this request is denied in whole or part, we ask that you provide a *Vaughn* index of withheld documents by (1) identifying each document withheld, by category above (and where fairly possible, by sub-categories 1-18, as well); (2) stating the statutory exemption claimed; and (3) explaining how disclosure would damage the interests protected by the claimed exemption. *See, e.g., Kimberlin v. DOJ*, 139 F.3d 944, 949-50 (D.C. Cir. 1998). Please notify me of appeal

---

<sup>2</sup> "The United States Patent and Trademark Office (USPTO), which is established as an agency of the United States within the Department of Commerce, operates under its own FOIA regulations at 37 CFR part 102, subpart A. Accordingly, requests for USPTO records should be sent directly to the USPTO." 15 C.F.R. § 4.4 n.1.

Robert Fawcett  
November 9, 2007  
Page 5

procedures available under the law. If you have any questions about handling this request, you may telephone me at (610) 270-5484.

This request seeks more documents than those sought under a separate FOIA request we filed yesterday. A form of expedited treatment is sought for the materials relevant to yesterday's request. That request is intended to take priority, and we respectfully ask that yesterday's request not be combined with this request or otherwise delayed on account of this request.

Sincerely,

A handwritten signature in black ink that reads "Mark Rachlin". The signature is written in a cursive, flowing style.

Mark Rachlin  
Senior Patent Counsel  
GlaxoSmithKline