

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

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TRIANTAFYLLOS TAFAS,	:	
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	:	
Plaintiff,	:	
	:	
v.	:	1:07cv846 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

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CONSOLIDATED WITH

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SMITHKLINE BEECHAM	:	
CORPORATION,	:	
d/b/a GLAXOSMITHKLINE, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	1:07cv1008 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

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GLAXOSMITHKLINE’S MEMORANDUM IN SUPPORT OF ITS MOTION TO  
COMPEL LIMITED DISCOVERY FROM THE DEFENDANTS TO COMPLETE THE  
ADMINISTRATIVE RECORD

## INTRODUCTION

Plaintiff GlaxoSmithKline (“GSK”) respectfully requests that the Court allow GSK to take limited discovery of the Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively, the “PTO”) to complete the Administrative Record. Despite the PTO’s mantra that the Administrative Record is “10,000 pages” and that the Final Rules are “127 pages,” the Administrative Record is facially incomplete.

For example, the Administrative Record is almost entirely devoid of documents from the critical time period leading up to the PTO’s publishing of the Proposed Rules in January 2006. Moreover, the Administrative Record contains fewer than 400 pages dated before the PTO published the Final Rules, despite the Proposed Rules’ substantial impact on patent application practice. Indeed, there are no documents dated earlier than January 2006 that discuss the major substantive aspects of the Proposed Rules, *e.g.*, the examination support document, the petition and showing requirement, or the rationale underlying the PTO’s decision to enact this sea change in patent prosecution practice. Instead, over 40 percent of the Administrative Record is comprised of public comments about the rules or slides from PTO presentations given to sell the rules to the public.

Furthermore, despite the overwhelmingly negative comments to the Proposed Rules, the Administrative Record contains hardly any correspondence with third parties or notes regarding communications with third parties (aside from the comments themselves). The Administrative Record contains little, if any, discussion of why the PTO changed the limit on claims and the limits on continuing applications. Finally, the Administrative Record includes little discussion or analysis of alternatives to the Final Rules; and the few documents provided on this point fail to explain why the PTO rejected those alternatives. It is as if the Proposed Rules were spontaneously conceived. “Only in Greek mythology did Athena spring full-grown from the

forehead of Zeus. Mortals require planning and preparation for such a birthing event.” *Tancogne v. Tomjai Enters. Corp.*, 408 F. Supp. 2d 1237, 1248 (S.D. Fla. 2005).

Here, GSK asserts, for example, that the PTO acted in an arbitrary and capricious manner in promulgating the Final Rules. As to that claim, the Court must analyze the PTO’s decision-making process to determine whether the PTO considered the appropriate factors and whether the PTO made a clear error of judgment. To make that determination, the Court must consider the “whole” record. Despite the PTO’s obligation to provide the “whole” record, it has not done so, hobbling this Court’s ability to review the PTO’s actions.

In situations, such as here, where the Administrative Record is so clearly incomplete, limited discovery is proper. GSK is not attempting to turn the PTO inside out with overbroad discovery requests. At this point in time, GSK seeks limited discovery in several identifiable and narrow categories to ensure that it and the Court evaluate GSK’s claims based on a complete record.<sup>1</sup>

### **BACKGROUND**

On January 3, 2006, the PTO issued two separate notices of proposed rule making in the Federal Register (“the Proposed Rules”). The PTO’s first Notice of Proposed Rule Making related primarily to continuing patent applications and requests for continued examination (“RCE”) of rejected patent applications. 71 Fed. Reg. 48 (Jan. 3, 2006). Specifically, the PTO proposed limiting applicants to a single continuing application before requiring that the applicant file a petition “showing to the satisfaction of the Director that the amendment, argument, or

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<sup>1</sup> To that end, GSK has attached hereto sets of document requests and interrogatories as Exhibits A and B, respectively, which it seeks the Court to order the PTO to satisfy. The discovery requests are narrowly tailored to remedy the deficiencies in the Administrative Record. At this point, GSK does not seek discovery via other mechanisms but may seek other discovery in the future if the Defendants’ discovery responses reveal the need to do so.

evidence could not have been submitted during the prosecution of the prior-filed application.” 71 Fed. Reg. at 59-60. The PTO also proposed limiting applicants to a single RCE before requiring the applicant to make a petition and showing. 71 Fed. Reg. at 61. The second Notice of Proposed Rule Making proposed significant changes to existing patent application practice by limiting an applicant to the examination of only ten representative claims. 71 Fed. Reg. 61, 67-68 (Jan. 3, 2006). If an applicant wanted the PTO to examine more than ten “representative claims,” then the applicant would be required to submit an onerous examination support document (“ESD”). *See* 71 Fed. Reg. at 67-68. The PTO also set forth proposed rules regarding the ESD, requiring, for example, a statement that a pre-examination search was conducted; an information disclosure statement citing the reference or references deemed most closely related to the subject matter of each designated claim; and for each cited reference, identification of all limitations of the designated claims found in the reference or references; and a detailed explanation of how each of the designated claims are patentable over each cited reference. *See* 71 Fed. Reg. at 68-69.

By May 3, 2006, the PTO received more than 500 comments to the Proposed Rules, critiquing both the substance of the Proposed Rules and offering constructive alternatives. The comments were overwhelmingly negative. GSK and others commented that the Proposed Rules would damage their business and stifle innovation and that the PTO lacked the statutory authority to promulgate the Proposed Rules. The PTO spent the next fifteen months reworking the Proposed Rules.

On August 21, 2007, the PTO published the Final Rules. 72 Fed. Reg. 46,716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1). In the Final Rules, the PTO limited applicants to two continuing applications (rather than one) before requiring a petition and showing. *Id.* at 46,839.

In relevant part, the PTO did not change its proposed rule limiting applicants to a single RCE before requiring a petition and showing. *Id.* at 46,841. Further, in the Final Rules, the PTO drastically changed the proposed rule limiting applicants to ten “representative” claims, opting to limit the number of independent claims and total claims to five and twenty-five (5/25), respectively, that an applicant could file without triggering the onerous ESD requirement. *Id.* at 46,836-37. Finally, the Final Rules imposed these limits retroactively. *Id.* at 46,716-17. Since August 21, 2007, in a failed effort to fix many of the problems of the Final Rules, the PTO has issued well over 200 pages of guidance documents purporting to explain the Final Rules and attempting to incorporate portions of its *Manual of Examining Procedure* (“MPEP”) into the Final Rules.

### **ARGUMENT**

#### **A. The Law Allows Private Parties To Take Limited Discovery Of An Agency To Complete The Administrative Record.**

This case arises under the Administrative Procedures Act (“APA”), pursuant to which the Court will review the PTO’s actions to determine if they were, among other things, “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). The APA requires that in making that determination, “the court shall review the whole record or those parts of it cited by a party.” 5 U.S.C. § 706. Here, the PTO has hindered the Court’s ability to review the entirety of the PTO’s actions because it has not yet produced the “whole record.”

Under the arbitrary and capricious standard, a critical inquiry is “whether the [agency’s] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Citizens to Preserve Overton Park, Inc. v Volpe*, 401 U.S. 402, 416 (1971).

Although the Court reviews the agency's decision with some deference, the Court must engage in a "substantial inquiry," *i.e.*, "a thorough, probing, [and] in-depth review." *Id.* at 415.

Generally, judicial review of an agency's actions is limited to the Administrative Record. *Camp v. Pitts*, 411 U.S. 138, 142 (1973). "The complete administrative record consists of all documents and materials directly or indirectly considered by the agency." *Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993). "An agency may not unilaterally determinate what constitutes the Administrative Record, nor can the agency supplement the Administrative Record submitted to the district court with post hoc rationalizations for its decision." *Miami Nation of Indians v. Babbitt*, 979 F. Supp. 771, 775 (N.D. Ind. 1996). Further, an "agency may not skew the record in its favor by excluding pertinent but unfavorable information." *Fund for Animals v. Williams*, 391 F. Supp. 2d 191, 197 (D.D.C. 2005).

As this Court recognized at the November 16, 2007 hearing, limited discovery may be appropriate in APA cases. *See, e.g., Shipbuilders Council of Am., Inc. v. U.S. Dep't of Homeland Security*, No. 1:07cv665, Order, Dkt # 92 (ordering limited discovery, including production of documents, an interrogatory answer, and a privilege log). When a party has shown "that the record may not be complete, limited discovery is appropriate" to complete the record. *Miami Nation of Indians*, 979 F. Supp. at 775 (quoting *Bar MK Ranches*, 994 F.2d at 740). Also, as this Court has recognized, "even in APA record review cases, circumstances may justify expanding the record or permitting discovery." *Am. Canoe Ass'n, Inc. v. EPA*, 46 F. Supp. 2d 473, 477 (E.D. Va. 1999) (citation omitted). Circumstances that justify expanding the record or permitting discovery may include: (1) "such a failure in the record to explain administrative action as to frustrate judicial review"; (2) "the agency's reliance on materials or documents not included in the administrative record"; or (3) "the need to supplement the record to explain or

clarify technical terms or other difficult subject matter included in the record.” *Id.* (citing *Public Power Council v. Johnson*, 674 F.2d 791, 793 (9th Cir. 1982)).

**B. The Current Administrative Record Is Incomplete.**

The current Administrative Record that the PTO provided cannot be complete, as it is missing documents from critical time frames and lacks documents discussing or analyzing critical substantive aspects of the Proposed Rules and the Final Rules.

**1. The Administrative Record Contains A Very Limited Number Of Documents Dated Before The PTO’s Publication Of The PTO’s Proposed Rules.**

The PTO published its Proposed Rules to limit continuing applications and claims on January 3, 2006 (the first business day in 2006 after the Federal New Years’ Day Holiday). Yet, the present version of the PTO’s Administrative Record includes very few documents (55) dated in 2005. The Administrative Record contains no information as to: (1) when the PTO formulated the proposed restrictions on continuing applications, RCEs, and claims; (2) the PTO’s rationale underlying its decision to restrict continuing applications, RCEs, and claims; (3) the PTO’s bases for selecting the specific proposed numeric limitations on continuing applications, RCEs, and claims; (4) the identity of any alternatives that the PTO considered when formulating the Proposed Rules; or (5) any analyses that the PTO performed when formulating the Proposed Rules, including assumptions, models, populations considered, and the like.

Moreover, the present Administrative Record does not contain any documents or information dated before January 3, 2006 regarding major substantive aspects of the PTO’s Proposed Rules. More specifically, the Administrative Record completely lacks any documents pertaining to the PTO’s original claim proposal, which would have limited an applicant to ten “representative” claims, or any other proposals that the PTO considered in advance of publishing the Proposed Rules. The present Administrative Record does not contain any documents

discussing the ESD requirement that are dated prior to publication of the Proposed Rules. Finally, the Administrative Record is devoid of any documents dated before January 3, 2006 describing the PTO's proposed petition and showing requirement, which is a vital component of the PTO's proposed limits on continuing applications and RCEs.

Documents that the PTO has provided in the Administrative Record show that other information is missing. For example, Exhibit C refers to a data run regarding continuing applications that was completed as of January 2005. (Ex. C at A03531.) Despite this reference, there are no e-mails to support that fact or any communications contemporaneous with that original data run. Another example demonstrates that, as of March 10, 2005, the PTO appeared to be contemplating a limit of six independent claims and fifty-one total claims. (Ex. D at A03554.) There is nothing in the Administrative Record, however, that evidences the 6/51 claim limit or the PTO's rationale for switching to the proposed "ten" representative claims limit. For the first time, in a document dated June 16, 2005, the Administrative Record references a "Final Rules package on claims limitations . . . and continuing applications." (Ex. E at A03764.) The Administrative Record does not contain any description of the rules at that point in time or any alternatives that were then under consideration. Moreover, in an October 21, 2005 e-mail, there is a reference to the "proposed continuation limitation rules" (Ex. F at A04387), but the Administrative Record does not contain any documents identifying or explaining the proposal as it then existed.

**2. The Administrative Record Is Missing Information Regarding The Changes From The Proposed Rules To The Final Rules.**

The Administrative Record is also missing documents for the time period between January 3, 2006 and August 21, 2007, the time during which the PTO made substantial changes to the Proposed Rules to arrive at the Final Rules. For example, the Administrative Record is



devoid of any information showing when the PTO formulated the changes that resulted in the Final Rules. It further lacks any information as to why the PTO made the changes it did. The Administrative Record includes little information on the alternatives that the PTO considered when making the changes. Finally, the Administrative Record lacks key analyses (including assumptions, models, populations considered, and the like)<sup>2</sup> that the PTO performed (or at the very least should have performed) leading to the changes included in the Final Rules.

As to the PTO's Final Rules limiting continuing applications and RCEs, the record lacks information regarding when the PTO decided to raise the limit from one continuing application as of right (as in the Proposed Rules) to two continuing applications as of right (as in the Final Rules). While the PTO did not change the number of RCEs an applicant could file from the Proposed Rules to the Final Rules, there is no discussion in the Record that purports to even consider the strong negative response to the proposed RCE rule. Finally, there are no documents in the Administrative Record describing the petition and showing requirement.

Regarding the changes in the claim limitation rule (from the examination of ten "representative" claims to a cap of 5/25), the Administrative Record is also incomplete. Despite the drastic shift in the scope of the rule, the Administrative Record does not contain any references to the new 5/25 claim limit for nearly an entire year from the close of the comment period on May 3, 2006. The first reference appears on March 21, 2007. (Ex. H at A05023.) While the PTO has attempted to minimize the drastic impact of the 5/25 claim limit by asserting that an applicant is allowed a total of fifteen independent claims and seventy-five total claims

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<sup>2</sup> It is important that completion of the Administrative Record be ordered to include those assumptions, models, populations, and the like considered because the PTO has itself conceded, at least internally, that "[i]t is very confusing as to what is included, what is being excluded, whether we're double counting, etc." (Ex. G at A04565.)

over three separate, but related, applications, the first time that the Administrative Record references this aspect is on May 1, 2007—more than one year after the Proposed Rules. (Ex. I at A05036.)

As for the ESD, the Administrative Record contains documents that make conclusory statements regarding the time estimates for preparing an ESD, but there is nothing that supports these conclusions. (*See, e.g.*, Ex. J at A08232 (PTO official Robert Bahr estimated that it would take 24 hours to prepare an ESD based, in part, on his “sense” that 24 hours was an appropriate amount of time.)) The Administrative Record, however, contains little else regarding the pre-examination search report, which is the most costly (and ambiguous) aspect of the ESD requirement. The Administrative Record also does not link the ESD’s mandatory pre-examination search to the MPEP, which the PTO has done subsequently in guidance documents and in this litigation in an attempt to clarify the mystifying rules.

**3. The Administrative Record Does Not Contain Any Documents Concerning the PTO’s Post-Promulgation Guidance On The ESD Requirement.**

Realizing that the new pre-examination search requirement is hopelessly vague, the PTO has issued substantial post hoc guidance to clarify this portion of the Final Rules. (*See* Defs.’ Opp. Pls.’ Mot. TRO and Prelim. Inj. at 36-37 (“[The] USPTO has published official guidance providing further explanation regarding the scope of the pre-examination search requirement.” (citations omitted)).) In fact, the PTO’s heavy reliance on this post hoc guidance to explain the ESD requirements underscores the vagueness of the ESD rules as promulgated on August 21, 2007. (*See id.*) Moreover, in the Final Rules, the PTO “explicitly informed the public that such official guidance would be forthcoming.” (*See id.* at 37 n.27.) In view of the PTO’s attempt to rely on post-promulgation guidance, documents relating to such guidance are part of the Administrative Record and GSK should be permitted discovery to complete this aspect of the

Administrative Record. Moreover, GSK should also be permitted to discover the PTO's internal communications and deliberations made after August 21, 2007 relating to this guidance and the ESD requirement because communications made after the PTO's promulgation of the Final Rules are not protected by the deliberative process privilege. *See Miami Nation of Indians*, 979 F. Supp. at 778.

**4. The Administrative Record Is Also Missing Many Documents Concerning Communications With Third Parties.**

Aside from the comments received in connection with the Proposed Rules, communications between the PTO and third parties are conspicuously absent from the Administrative Record. For example, the Administrative Record contains evidence of few communications between the PTO and Congress, or other agencies in the Executive branch. There are also very few communications between the PTO and members of the general public, such as the media, commentators, professors (including academics, of any sort), or businesses, despite the controversy that the Proposed Rules sparked. There are few, if any, notes, records, or memoranda concerning any communications between the PTO and any third-party (governmental or private).

Numerous documents in the Administrative Record reveal the absence of other documents and information from the record. For example, an April 25, 2007 e-mail from John Collier at ICF International to Amber Ostrup at the PTO, with copies to PTO officials Robert Bahr and Jennifer McDowell, indicates that ICF learned in January 2007 that the claims rule would affect a higher percentage of applicants than originally thought and that "AB93 [the proposed rule relating to continuing applications and RCEs] would not be enacted." (Ex. K.) There is nothing in the Administrative Record detailing this information that ICF learned or how ICF learned of this information. More importantly, there is nothing in the Administrative Record

indicating why the PTO (as of January 2007) had determined not to enact the continuing applications rule (AB93), but eventually wound up promulgating the continuing applications rule in the Final Rules it published in August 2007.

This e-mail also mentions that “the scope of the ESD was back to what it had been previously” (*id.*), but the Administrative Record contains no references to changes in the scope of the ESD requirement nor any communications between the PTO and ICF detailing these changes. That same e-mail also references ICF’s “first task order” and “second task order” (*id.*), but the record does not include these orders. The e-mail in question also references an inquiry from the U.S. Small Business Administration (“SBA”) and the PTO’s need to discuss the SBA’s inquiry with ICF (*id.*), but the record does not indicate the nature of the SBA’s inquiry, or whether the referenced follow-up with ICF ever occurred, or what the contents of those communications were, if they occurred. Finally, that e-mail refers to a “meeting with SBA” (*id.*), but the record is devoid of any notes or records regarding the PTO’s meeting with SBA.

In an e-mail dated April 2, 2007, ICF requested that the PTO send to ICF a “Patenting Trends Report.” (Ex. L.) In a responsive communication, the PTO indicates that it sent the report to ICF on April 2, 2007. (*Id.*) Thus, the PTO had a copy of the report. (*Id.* (“I have the Patenting Trends Report you requested. It is on a CD.”)) The report, however, is not included in the Administrative Record.

Also missing from the record are comments provided by the Office of Advocacy of the SBA regarding the PTO’s rules. Exhibit M is an e-mail string between the PTO and the SBA. In a June 29, 2007 e-mail, the SBA indicates that it has “reviewed the new language and thinks it looks really good” and states that “Advocacy has no further comments or changes.” (*Id.*) However, the PTO has not included the old language it sent to SBA or the SBA’s prior

“comments or changes” in the Administrative Record. Reference to the SBA’s input appears curiously one-sided and anticlimactic.

**5. The Administrative Record Does Not Contain Any Analyses Or Discussions Regarding Alternative Claims Rules That The PTO Considered.**

The Administrative Record contains little, if any, of the PTO’s analyses, discussions, or consideration of less-burdensome alternatives to limiting claims or alternative numerical limits on claims. (*See, e.g.*, Ex. N (mentioning the percentage of applications in 2005 and 2006 that would exceed more than 6 independent and 20 total claims; more than 5 independent and 25 total claims; more than 6 independent and 30 total claims; and more than 6 independent and 40 total claims).) The Administrative Record also does not contain any analysis or discussion of the vast difference in impact between the proposed ten “representative” claims rule (1.2% of applications) and the 5/25 claim limit in the Final Rules (25% of applications). *Compare* 71 Fed. Reg. at 62 *with* Ex. N. The absence of analysis and discussion is particularly conspicuous since the changes to the claims rule from proposed to final caused ICF to make “significant changes to [their] analysis and spreadsheets.” (Ex. N.)

**C. Allowing GSK Limited Discovery To Complete The Administrative Record Is Proper.**

As the foregoing demonstrates, the Administrative Record is incomplete. The lack of completeness is, unfortunately, a growing trend in this litigation. As yesterday’s GSK filing regarding the necessity of a privilege log indicated, there is a palpable sense from the PTO that the basic rules of federal and administrative procedure, generally applicable to all parties, do not, for some reason, apply to them. An Order permitting limited discovery, coupled with one requiring the furnishing of a privilege log for what has been withheld, will restore this case to its

rightful path, and clear the way for what is truly important, the resolution of the dispute on the merits.

GSK is not on a random hunt for documents in this Motion. Instead, GSK is merely requesting that the PTO provide discovery to complete the Administrative Record, which is supposed to include “all materials relevant to the agency’s contemporaneous construction of its regulations.” *Tenneco Oil Co. v. Dep’t of Energy*, 475 F. Supp. 299, 318 (D. Del. 1979) (“The internal memoranda, directives and guidelines generated and disseminated at a variety of levels are proper items of discovery.”). Thus, GSK requests that the Court order the PTO to respond to the document requests attached hereto as Exhibit A and the interrogatories attached hereto as Exhibit B.

GSK’s document requests are narrowly-tailored to achieve the goal of completing the record. The requests address the following categories: (1) limits on claims, continuing applications, and RCEs; (2) the petition and showing requirement of the continuing application and RCE limitations; (3) the ESD; (4) alternatives to the Final Rules; (5) communications with third parties, whether separate government agencies or private entities of any kind; (6) the PTO’s decision to link the MPEP to the ESD requirement; (7) the guidance that the PTO issued after promulgating the Final Rules; (8) the impact on different industries or technologies; (9) any models that the PTO used, including explanations thereof; and (10) all data used by the PTO in the models. Requiring the PTO to comply with these narrowly-tailored document requests will allow the Plaintiffs, and this Court, to evaluate the propriety of the PTO’s actions in view of a complete Administrative Record.

**CONCLUSION**

For the foregoing reasons, GSK respectfully requests that this Court order the Defendants to produce all non-privileged documents relevant to the Proposed Rules and Final Rules as identified above.

Date: November 20, 2007

Respectfully submitted,

/s/

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I hereby certify that a true copy of the foregoing pleading was filed electronically this 20th day of November 2007 using the CM/ECF system, which will send notification by electronic means to the following counsel of record:

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