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CORPORATE INTELLECTUAL PROPERTY

To: Attn: Nicole for
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General Counsel
United States Patent and
Trademark Office
P.O. Box 15667
Arlington, VA 22202

From: Sherry M. Knowles
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Date: October 10, 2007

Subject: Verified Complaint

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October 10, 2007

VIA FACSIMILE

Re: Verified Complaint

James A. Toupin, Esq.
General Counsel
Stephen Walsh, Esq.
Acting Deputy General Counsel and Solicitor
United States Patent and Trademark Office
P.O. Box 15667
Arlington, VA 22202

Dear Mr. Toupin and Mr. Walsh:

I attach a Complaint that was filed in the U.S. Federal Court for the Eastern District of Virginia yesterday against the US Patent and Trademark Office to challenge the Final Rules published on August 21, 2007 (72 Fed. Reg. 46716-46843) that limit patent continuation and claims practice. GSK has strong respect for the US Patent and Trademark Office, and would welcome a conversation or meeting with you about this matter. Please feel free to contact me.

Sincerely,

A handwritten signature in black ink that reads "Sherry M. Knowles". The signature is written in a cursive, flowing style.

Sherry M. Knowles, Esq.

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

SMITHKLINE BEECHAM
CORPORATION,
d/b/a GLAXOSMITHKLINE,
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED, d/b/a
GLAXOSMITHKLINE,

Plaintiffs,

v.

JON W. DUDAS, in his official capacity
as Under Secretary of Commerce
for Intellectual Property and Director
of the United States Patent and
Trademark Office, and

UNITED STATES PATENT AND
TRADEMARK OFFICE,

Defendants.

Civil Action No. _____

VERIFIED COMPLAINT

Plaintiffs SmithKline Beecham plc, SmithKline Beecham Corporation d/b/a
GlaxoSmithKline, and Glaxo Group Limited d/b/a GlaxoSmithKline (collectively referred to as
"GSK") for their Complaint against Defendant Jon W. Dudas, in his official capacity as Under
Secretary of Commerce for Intellectual Property and Director of the United States Patent and
Trademark Office, and Defendant United States Patent and Trademark Office ("PTO"), hereby
allege as follows:

I. INTRODUCTION

1. On August 21, 2007, the Department of Commerce, Patent and Trademark Office (“PTO”) published Final Rules titled “Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications.” These Final Rules revise the rules of practice in patent applications relating to continuing applications, requests for continued examination, and for the examination of claims in patent applications. 72 Fed. Reg. 46716, 46716-47843 (Aug. 21, 2007).

2. These Final Rules amend, among other sections, 37 C.F.R. §§ 1.75, 1.78, and 1.114, and add 37 C.F.R. § 1.265. The changes to §§ 1.75 and 1.265 apply to any nonprovisional application pending on or after November 1, 2007 that has yet to receive a first Office Action on the merits. 72 Fed. Reg. at 46716. The changes to § 1.78, except for those changes to §§ 1.78(a) and 1.78(d)(1), apply to any nonprovisional application pending on November 1, 2007. *Id.* at 46717. The changes to § 1.114 apply to any application in which a request is made after November 1, 2007. *Id.* Thus, the changes affect GSK patent applications that have already been filed and are pending in the PTO. *Id.* at 46717.

3. Plaintiff GSK respectfully requests that the Court preliminarily and permanently enjoin the PTO from implementing the Final Rules on November 1, 2007 or thereafter as the Final Rules were promulgated without proper legal authority. The Final Rules are also vague, arbitrary and capricious, and prevent GSK from fully prosecuting patent applications and obtaining patents on one or more of its inventions.

4. The PTO’s promulgation of the Final Rules will damages specific GSK patent applications and inventions. Presently, GSK has approximately one hundred or more pending applications in which two or more continuations or continuations-in-part have been filed, and

approximately thirty or more pending applications in which two or more continuations or continuations-in-part and a request for continued examination have been filed.

5. The PTO should be enjoined from implementing the Final Rules because Congress has not empowered the PTO to promulgate such regulations. The PTO, as a federal governmental agency, obtains its power solely at the discretion and prerogative of Congress, which is embodied in 35 U.S.C. § 2. Congress obtains its power in this area from the United States Constitution: “The Congress *shall have Power . . .* To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries” U.S. Const. art. I, § 8, cl. 8 (emphasis added). Congress has utilized its powers and enacted laws, which do not grant the PTO the authority to restrict the number of continuing applications, requests for continued examination, or claims that may be filed. Thus, by issuing final regulations that set forth binding and mandatory rules that impose such restrictions, the PTO engaged in *ultra vires* rulemaking.

6. Under the patent laws, a patent applicant is permitted to file a continuing application so long as certain formal requirements (e.g., referring back to prior-filed applications) are met. The Final Rules, however, abrogate an applicant’s ability to file continuing applications by restricting an applicant to two such applications before the applicant is required to file a petition “showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application.” 72 Fed. Reg. at 46839. The PTO intends to apply this limit retroactively—that is, to applications that have already been filed before the effective date of the Final Rules

7. In explaining this new petition and showing requirement in response to comments, the PTO has made clear that the “could not have” evidentiary burden in almost all

cases precludes not just the grant of a petition, but the actual filing of a petition itself. *See id.* at 46767-46779. The “could not have” standard poses a Hobson’s choice under the PTO’s rules of professional conduct, especially 37 C.F.R. § 10.85(a)(5), which bars a practitioner from knowingly making a false statement of law or fact. Violations of § 10.85(a)(5) may result in reprimand, suspension, or exclusion of practice before the PTO. *See* 37 C.F.R. § 10.131. Because the PTO construes the term “could not have” in its ordinary sense of meaning, i.e., that one could not have physically presented the amendment, evidence or argument, GSK would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition. This conflict renders compliance with the PTO’s new petition requirement extremely difficult, if not impossible, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations as well as the “could not have” standard. As a result, the PTO’s petition and showing represents a regulatory trap, except in the case where the PTO requests data from an applicant and the applicant diligently acquired data demonstrating unexpected results and desired to submit the data to rebut a new PTO rejection that the claims are obvious over the prior art.

8. The patent laws also allow applicants to file a request for continued examination (“RCE”) of an application and require that the PTO continue such examination when requested to do so. The Final Rules, however, impose substantive restrictions on an applicant’s ability to file such requests for continued examination and, in doing so, the Final Rules exceed the PTO’s authority. Indeed, the Final Rules allow an applicant only one RCE before requiring the applicant to submit a petition showing that “the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application . . .” 72 Fed. Reg. at 46841-42. Again, the PTO will be applying this provision retroactively to pending applications. As with the proposed limit on continuations, GSK, along with many other

parties, submitted comments to the PTO demonstrating that, if the agency imposed any restrictions upon requests for continued examination, it would be acting beyond its statutory authority and harming important intellectual property interests.

9. The patent laws specifically allow an applicant to file "one or more claims," so long as the claims meet the requirements for patentability. 35 U.S.C. § 112, ¶ 2. In sharp contrast, the Final Rules impose unlawful restrictions and limits on the number of claims an applicant may submit before being required to submit an onerous "examination support document." The PTO will apply this new restriction and limitation retroactively to any application pending that has yet to receive a first Office Action on the merits from the PTO. In substantively restricting an applicant's rights to claim their inventions, the PTO has exceeded its authority and will cause affected applicants irreparable harm.

10. In another pending suit in this Court, *Triantafyllos Tafas vs. John Dudas and the United States Patent and Trademark Office* (1:07cv846), Plaintiff Tafas has alleged that the PTO's promulgation of the Final Rules will cause him harm. Defendants in the *Tafas* litigation, which are the same as the present Defendants, filed a Partial Motion to Dismiss and a Memorandum in Support of Defendants' Partial Motion to Dismiss on October 4, 2007. While the *Tafas* allegations and the Defendants' responses to those allegations are distinct, separate and independent from GSK's present allegations, GSK refers herein to certain aspects of Defendants' Memorandum in Support for case of reference for the Court.

11. Specifically, the Director and the PTO have taken the position that one may not be able to establish harm caused by the Final Rules except by demonstrating specific examples of harm caused to pending patent applications. While GSK amply meets this burden, the Director's and the PTO's position is convenient but incorrect, because it runs contrary to the

two-part ripeness test established in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), which permits preenforcement review of agency regulations where the questions presented are fit for judicial review and would pose a hardship to regulated parties. Here, the PTO's authority to promulgate rules is both granted and limited by 35 U.S.C. § 2. The PTO "may establish regulations, **not inconsistent with law**, which shall govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b) (2006) (emphasis added). Under this single statutory grant of rulemaking power, the PTO can only promulgate rules that fall squarely within the bounds of established statutory patent law. It has exceeded its authority in promulgating the Final Rules, thereby posing a fit question for preenforcement review under *Abbott Laboratories*.

12. The Final Rules clearly apply to a domain of regulated parties such as GSK because GSK regularly applies for patents using continuing applications and requests for continued examination, as well as requests the examination of multiple claims in its patent applications. The Final Rules would require GSK "either to expend non-recoverable resources in complying with a potentially invalid regulation or to risk subjection to costly enforcement processes," *Seegers v. Gonzales*, 396 F.3d 1248, 1253 (D.C. Cir. 2005), and hence pose a hardship to GSK that permits preenforcement review. In *Abbott Laboratories*, the Supreme Court permitted the preenforcement review of Food and Drug Administration labeling and advertising regulations for drugs. Here, the legal questions presented threaten not just added costs from compliance with ancillary marketing restrictions, but whether the life-saving drugs innovated by GSK and other similarly situated members of the pharmaceutical industry will be invented in the first place, given changes to the patenting system sought to be imposed by the PTO.

13. On September 7, 2007, the House of Representatives passed H.R. 1908. Section 14 of H.R. 1908 amends Title 35 to add § 2(c)(6), which grants the PTO “authority to promulgate regulations to insure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121 and 365(c) of the filing date of prior filed application for patent.” Section 14 of H.R. 1908 further states that any regulations passed under 2(c)(6) can not take effect before the end of sixty days after the Director submits to each House of Congress a copy of the regulation. If a joint resolution of disapproval is passed, the regulation shall not become effective. The Senate is considering S. 1145, which unlike H.R. 1908, rightly does not include a grant of similar rulemaking authority to the PTO. Based on this legislative action, it is clear that: (i) While the House of Representatives couches the provision as a clarification of existing law, Congress has not yet granted the PTO the authority to make rules of practice that restrict continuing applications—if Congress had already given the PTO such authority in 35 U.S.C. § 2, then Section 14 of H.R. 1908 would be redundant and meaningless; (ii) The House of Representatives takes the position that the PTO should not promulgate such rules until Congress has been given 60 days to consider and perhaps disapprove them; (iii) The Senate correctly and appropriately has not followed the House of Representatives to date in approving a bill that grants the PTO this rulemaking authority; and (iv) The issue of PTO rulemaking authority is still subject to significant congressional debate, has not been agreed upon, and, indeed, may never be agreed to in the future. The PTO cannot bypass the political process by promulgating rules when Congress has not given that rulemaking authority to the PTO.

14. The Final Rules also pose an unconstitutional arbitrary and capricious regulatory taking of GSK’s patent and patent application property rights. Patents and patent applications

are constitutionally protected private property. See 35 U.S.C. § 261; *Consolidated Fruit-Jar Co. v. Wright*, 84 U.S. 92, 96 (1876) (“A patent for an invention is as much property as a patent for land.”); *Winchester v. Commissioner*, 27 B.T.A. 798, 1993 WL 231 (Bd. Tax. App. 1933) (“It is now well settled that patent applications are property.”); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (finding that intellectual property, such as a trade secret, is constitutionally protected private property). By imposing arbitrary restrictions on GSK’s ability to prosecute its patent applications, the Final Rules diminish greatly the value of GSK’s pending and future patent applications by depriving GSK the ability to claim fully and completely its inventions, resulting in an unconstitutional taking. The PTO has acted arbitrarily and capriciously in failing to adequately consider such issues in the rulemaking process.

15. The Final Rules are so vague that they are incapable of being complied with and do not put GSK on sufficient notice of what it must do to comply. Under new 37 C.F.R. § 1.75(b)(1), if an application contains more than five independent claims and/or twenty-five total claims, an applicant must file an examination support document (“ESD”) in compliance with new 37 C.F.R. § 1.265. 72 Fed. Reg. at 46836.

16. Newly created § 1.265 sets forth the requirements of an ESD, one of which, § 1.265(a)(1), requires that the applicant perform a preexamination search. *Id.* at 46842. Rule 1.265(b) sets forth requirements of a preexamination search as including the searching of “U.S. patents and patent application publications, foreign patent documents and non-patent literature.” *Id.*

17. Newly added § 1.265(b), however, does not provide any metes or bounds on the scope of the search and, as a result, GSK has no idea how to comply with this regulation. For instance, neither the rule nor the comments indicate whether the applicant must conduct

electronic searches, manual searches, or both; in which countries databases the applicant must search; or which libraries must be searched. Certainly, the cost of searching could be quite large and the rule does not set forth an expense cap or limitation. In light of the vagueness of § 1.265, GSK does not know how to comply with the rule and, therefore, the PTO should be enjoined from implementing the rule. The PTO has issued guidance documents, which are not regulations and do not cure the vagueness of the ESD requirement.

18. Newly amended § 1.75(b) also states that “[m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied.” 42 Fed. Reg. at 46836. The term “not unduly multiplied” is also vague and does not put GSK on sufficient notice of what is permissible. This kind of vague language can impermissibly be used at the discretion of the PTO to mean almost anything, and therefore is not a well-defined rule capable of compliance or consistent with the rational organization of business activities. Furthermore, the lack of clarity in the Final Rules will multiply the nonrecoverable compliance costs that GSK will experience under the new system the PTO seeks to establish without a statutory delegation for doing so.

II. JURISDICTION AND VENUE

19. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 1361.

20. GSK has standing to bring this suit because it is specifically and personally harmed by the Final Rules. Indeed, GSK’s standing is self-evident because it is a frequent user of the patent system and a directly regulated party. GSK is not an isolated inventor that may never innovate again, and GSK is not seeking to represent the interests of third-party inventors.

21. This matter is ripe because the issues GSK presents for review meet the *Abbott Laboratories* fitness and hardship requirements, and because GSK also has pending patent applications that are affected by the Final Rules.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c).
- a. The principal office of the Director and the PTO's headquarters are located in Alexandria, Virginia pursuant to 35 U.S.C. § 1(b).
 - b. The PTO conducted its *ultra vires* and unconstitutional rule making activities in Alexandria, Virginia at its headquarters and comments were solicited to the PTO in Alexandria, Virginia. Hence, the events giving rise to this action occurred in Alexandria, Virginia.
23. This case arises under causes of action created by the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*
24. Proper forms of relief in this action include, but are not limited to, the following:
- a. issuing preliminary and permanent injunctions under 5 U.S.C. § 703;
 - b. issuing declaratory relief under 5 U.S.C. § 703 and 28 U.S.C. §§ 2201-2202;
 - c. holding unlawful and setting aside the PTO's action (i.e., issuing a vacatur remedy) under 5 U.S.C. § 706(2); and
 - d. compelling the PTO to perform its duty under 28 U.S.C. § 1361.

III. THE PARTIES

25. Plaintiff SmithKline Beecham plc is a public limited company organized under the laws of England and Wales with its principal place of business at 980 Great West Road, Brentford, Middlesex, TW89GS, England.

26. Plaintiff SmithKline Beecham Corporation is a Pennsylvania corporation having its principal place of place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102 and doing business under the name GlaxoSmithKline.

27. Plaintiff Glaxo Group Limited, doing business as GlaxoSmithKline, is a company organized and existing under the laws of England and having an office and place of business at