GlaxoSmithKline

FAX

CORPORATE INTELLECTUAL PROPERTY

To: **Attn: Nicole for**
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2007 OCT 10 AM 11:06
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From: Sherry M. Knowles
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Date: October 10, 2007

Subject: Verified Complaint

Pages: 55 including this fax cover

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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,

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.	:	**Civil Action No. _____**
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.	:	

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, *Triantyfyllos 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 Dismisson 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 Laboratoriess 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 *Abott 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(e).

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 businss as GlaxoSmithKline, is a company organized and existing under the laws of England and having an office and place of business at

Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom. Plaintiffs SmithKline Beecham PLC, SmithKline Beecham Corporation, and Glaxo Group Limited are hereinafter collectively referred to as "GlaxoSmithKline" or "GSK".

28. Defendant PTO is an administrative agency of the United States Department of Commerce. The PTO's headquarters is located in Alexandria, Virginia. The PTO is responsible for granting and issuing patents and registering trademarks and disseminating information to the public regarding patents and trademarks. Among other things, the PTO is authorized to establish regulations "not inconsistent" with the patent laws which "govern the conduct of proceedings" before the PTO.

29. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and the Director of the PTO ("the Director") and is named in his official capacity. Under 35 U.S.C. § 3(a), the Director is charged with providing policy direction and management supervision for the PTO. The Director is also responsible for issuing patents and registering trademarks.

30. GSK researches, develops, tests, and markets life-saving medicines that treat some of the worst diseases, including cancer, cardiovascular disease, respiratory diseases such as asthma and chronic obstructive pulmonary disease, HIV, Alzheimer's, depression, and diseases of the emerging world such as malaria and tuberculosis. To get to the point of marketing these drugs, GSK spends hundreds of millions, and typically over one billion dollars, per new drug on human clinical trials where the entirety of GSK's investment is at risk due to the uncertainty of the clinical trial process, which results in many drugs never reaching the marketing phase. GSK also develops preventative medicines such as pediatric vaccines, cancer vaccines, and deadly bacteria vaccines and is currently in clinical trials to create preventative medicines for prostate

cancer, melanoma and cervical cancer. Under the current patent system and its well-established incentives, GSK has been able to bring many innovative and beneficial drugs to market. For example, over the past several years, GSK has brought to the American public Zofran, for alleviation of nausea and vomiting associated with chemotherapy and radiotherapy for cancer, Valtrex, for management of herpes simplex and herpes zoster, Advair for the prophylactic treatment of asthma and other airway obstruction disorders, and Coreg, for the treatment of mild-to-severe chronic heart failure. GSK is proud of its recent launch in the United States of Tykerb for the treatment of advanced stage and metastatic breast cancer after over ten years of research.

31. GSK undertakes enormous efforts to bring new drugs and products to market. The scientific research and discovery of a new drug and the following clinical development takes a decade or more of hard work and often a billion dollars in completely at-risk investment. The research and development of drugs is fraught with many hurdles, ultimately leading to thousands of rejected drugs (and wasted money) for each successful drug to market. Joseph A. Dimasi et. al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ.151 (2003). *See also* Christopher P. Adams et. al., *The Real Cost of Drug Development* (2006) available at http://www.touchbriefings.com/pdf/1842 /Chris_Adams.pdf.

32. GSK's drug products protect and support the health and life of American citizens. GSK has expended tremendous research investments to bring those drugs to market. The current patent laws encouraged GSK to invest in the discovery and development of those drugs, as well as new drugs currently under development, by providing robust patent protection. GSK's drug research necessarily requires a large, up-front, at-risk investment. That research involves sophisticated, high-level sciences, including organic chemistry and molecular biology, which require significant resources to generate innovative drugs. Further, the discovery and

development of those drugs through the time of approval can take up to ten years or more. During that time, additional or confirmatory information is often gathered about the drugs that GSK should be able to use to obtain strong patent protection. Without the guarantee of adequate patent protection, GSK's ability to innovate is compromised because it cannot afford to undertake the enormous research investments necessary to bring these drugs to market.

33. The Final Rules arbitrarily limit the ability to claim all aspects of new medical inventions and discoveries thereby reducing the incentive to innovate. That harms not just GSK; it causes substantial harm to the public interest by threatening the future health of American citizens.

IV. SUMMARY OF DISPUTE AND HARM CAUSED BY THE FINAL RULES

A. Continuation Patent Applications and the Changes Under the New Rules

34. An inventor has a statutory entitlement to a patent unless the invention that is the subject of the application for the patent is not new or is obvious. 35 U.S.C. §§ 102-03. To obtain a patent, an inventor must file a written application that contains a specification, an oath and "one or more" claims. 35 U.S.C. §§ 111-12.

35. The date of filing of each patent application is critically important. The applicant's entitlement to a patent, e.g., novelty under § 102 and non-obviousness under § 103, will be judged from the earliest filing date to which the application is entitled. By obtaining the earliest possible filing date, an applicant may establish that its patent application was filed before a similar application filed by someone else. The filing date also allows an applicant to

demonstrate that its application was filed before the date of publication of information (called prior art) that would have to be considered in evaluating patentability.[1]

36. 35 U.S.C. § 120 provides that a patent application filed by an inventor for an invention previously disclosed in a pending patent application "shall have the same effect, as though filed on the date of the prior application," if, among other things, it contains a specific reference to the prior application. Section 120 allows inventors to file chains of patent applications that relate back to a first filed application and entitle the later applications to the benefit of the filing date of the first filed application for each application in the chain. The applications filed after the first application are known as "continuation" applications. Thus, a continuation patent application is a patent application that stems from, and claims the benefit of the filing date of, an earlier-filed patent application. *See* 4A Donald S. Chisum, *Chisum on Patents* § 13.03 (2007). A continuation application contains the same disclosure as the original application.

37. The priority filing date is critical to GSK because it sets the stake in the ground on prior art references from which the PTO will analyze the patentability of the patent claims during prosecution (and, potentially, in later litigation). If the priority filing date is lost because GSK cannot claim the benefit of the filing date in a later-filed application, the later-filed application will only be entitled to its actual filing date, and the later-filed application will be analyzed against prior art that became available between the earlier-filed application and the later-filed application. In such situations, if the earlier-filed application is published as is often the case

[1] Defendants in the *Tafas* litigation provided a summary of the patent application process on pages 4 through 8 of their Memorandum in Support of Defendants' Partial Motion to Dismiss. GSK provides a copy of Defendants' summary as Attachment A to this Complaint for the Court's convenience.

under 35 U.S.C. § 122, then the earlier-filed application itself may become prior art against the later-filed application.

38. There have historically been numerous valid reasons to file continuation applications of earlier-filed patent applications in a manner that advances patent prosecution yet maintains the benefit of that critical early stake in the ground. For example, GSK files continuation applications to differentiate its invention from the prior art, following the unsuccessful submission of arguments that the patent examiner has not established a *prima facie* case of obviousness. GSK also files continuation applications containing rejected claims to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. *See, e.g, Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) (stating that it is proper to file a continuation application to submit evidence of unexpected advantage that did not exist at the time of the rejection). GSK also files continuation applications to add new claims directed to subject matter that is disclosed in the application, but which has not been claimed in a prior application for which examination has closed on the merits. The PTO has indicated that all the foregoing bases would be insufficient to carry the applicant's burden of showing that the argument or evidence "could not have been submitted earlier" under the final rules. 72 Fed. Reg. at 46772-77. The PTO has made these pronouncements despite the fact that the Federal Circuit has stated that GSK, or any applicant, "may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive." *See Symbol Techs.*, 422 F.3d at 1385.

39. In the past, GSK has also filed continuations to disclose new prior art, often times, as a result of the receipt of a "Search Report" from a foreign patent office during the examination

of a related foreign patent application. Applicants may submit references cited by a foreign patent office in a related application or face a later charge of inequitable conduct for failure to comply with the duty to disclose material information to the PTO during prosecution. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995) (finding inequitable conduct based on failure to submit references cited in a search report from the European Patent Office). The PTO, however, has indicated that, under the Final Rules, it will not accept a petition based on the disclosure of new prior art. 72 Fed. Reg. at 46773-74.

40. The Final Rules remove GSK's right to obtain the filing date of the first filed application for additional applications by limiting an applicant to two continuation 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 (emphasis added). The PTO has indicated that the following reasons for filing continuation applications, which were all normal, customary, sanctioned and accepted reasons for filing continuations prior to the Final Rules, are no longer adequate to support a petition: the applicant attempts to submit "newly discovered prior art" (Response to Comment 85), the examiner's interpretation of the claims is unusual and only recently understood by the applicant or the examiner changes his or her interpretation of claim language (Response to Comment 87), applicants have recently discovered a commercially viable product, financial resources, useful subject matter, a competing product, or similar or parallel technology on the market (Response to Comment 91), or the applicant becomes disabled for a lengthy time during the pendency of the application (Response to Comment 100). *Id.* at 46773-77.

41. The PTO intends to apply this limit retroactively—to applications that have already been filed before the effective date of the Final Rules. The PTO discriminates against already pending applications that include two or more continuations or continuations-in-part by arbitrarily allowing only "one more" continuation application (before an applicant is required to file a petition and showing).

42. In explaining the 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. For example, the "could not have" standard creates a dilemma for applicants and their counsel under 37 C.F.R. § 10.85(a)(5) in the PTO's rules of professional conduct, which bars a practitioner from knowingly making a false statement of law or fact. 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, and, as a result, 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 new 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.

B. Historical Background Regarding Continuation Applications

43. As early as 1863, the Patent Act was understood to allow an applicant to file continuation patent applications. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1963) (in interpreting the act of 1839, the Supreme Court recognized that "if a party choose to withdraw

his application for a patent . . . intending at the time of such withdrawal to file a new petition, and he accordingly do so, the two petitions are to be considered as parts of the same transaction, and both as constituting one continuous application . . .").

44. During the ensuing years, the law did not limit the number of continuation applications that may be filed. In discussing continuation applications, William Robinson's 1890 patent treatise noted that "[i]t is immaterial how many of these substituted applications may be filed, or for how long a period such efforts to obtain a patent may be continued." 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 581, at 204 (reprinted, 1972); *see also* 1 Walter F. Rogers, *The Law of Patents* 21 (1914) ("[N]o number of successive applications indicates an intention to abandon, . . . in reference to the question of abandonment, all such may be regarded as one application, the ones subsequent to the first being known as 'continuing' applications.").

45. In enacting 35 U.S.C. § 120 in the Patent Act of 1952, Congress codified the existing case law regarding continuations. According to the legislative history, Section 120 represented "present law not expressed in the statute, except for the added requirement that the first application must be specifically mentioned in the second." Senate Report No. 1979, June 27, 1952 (accompanying H.R. 7794), at 2413.

46. 35 U.S.C. § 120, as enacted in 1952, stated that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Act of July 19, 1952, Pub. L. 593, ch. 950, § 120, 66 Stat. 800, *reprinted in* 1952 U.S.C.C.A.N. 761.

47. After 35 U.S.C. § 120 was enacted, the Court of Customs and Patent Appeals—the predecessor court to the Federal Circuit—stated that the PTO could not limit the number of continuing applications that an applicant could file. *See In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968). The court stated that a patent examiner had "no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of co-pendency may be traced to obtain the benefit of the filing date of the earliest of a chain of co-pending applications, provided applicant meets all the other conditions of the [§120] statute." *Id.*

48. The PTO has stated that *Henriksen* "established that the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved." *Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975).

49. The Court of Customs and Patent Appeals also indicated that only Congress can limit the number of continuation applications. Specifically, the court stated that, "it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction [on continuation practice] . . . is to be imposed." *In re Henriksen*, 399 F.2d at 262. Further, in 1977, the Court of Customs and Patent Appeals reiterated that limiting "continuing applications is a matter of policy for the Congress . . . ." *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977).

50. After *Henriksen*, courts have continued to interpret Section 120 very broadly. *See In re Bauman*, 683 F.2d 405, 406-407 (C.C.P.A. 1982) (denying the PTO's ability to "require recognition of a nonstatutory exception to the clear language of § 120"); *Transco Products Inc.*

v. Performance Contracting, Inc., 38 F.3d 551, 556-557 (Fed. Cir. 1994) (not requiring a patent applicant to update its "best mode" disclosure when filing a continuation application, because it was not required under § 120's "plain and unambiguous meaning").

51. In 1999, Congress contemplated and altered the scope of the PTO Director's discretion under Section 120 to deny an application the benefit of a priority. *See* Pub. L. No. 106-113, § 4503(b)(1), § 120, 113 Stat. 1501, 1501A-563 to 1501A-564 (1999). Specifically, Congress added the following paragraph to Section 120:

> No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director ***may consider*** the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director ***may establish procedures***, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Id. (emphasis added). Thus, Congress explicitly granted the PTO *limited* authority to "empower the Director to: (1) establish a time by which the priority of an earlier filed United States application must be claimed; (2) consider the failure to meet that time limit to be a waiver of the right to claim such priority; and (3) accept an unintentionally late claim of priority subject to the payment of a surcharge." 145 Cong. Rec. S14,719 (daily ed. Nov. 17, 1999). Congress did not grant the PTO any other discretionary powers.

C. GSK's Use of the Patent Application Process During Drug Research and Development

52. GSK undertakes enormous efforts to bring new drugs and products to market. The scientific research and discovery of a new drug and the following clinical development takes a decade or more of hard work and often a billion dollars in completely at-risk investment. The research and development of drugs is fraught with many hurdles, ultimately leading to thousands of rejected drugs (and wasted money) for each successful drug to market. Joseph A. Dimasi et.