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

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

CONSOLIDATED WITH

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

MEMORANDUM IN SUPPORT OF GLAXOSMITHKLINE'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION.

Plaintiffs SmithKline Beecham Corporation and Glaxo Group Limited d/b/a GlaxoSmithKline, and SmithKline Beecham plc (collectively, "GSK") are entitled to judgment as a matter of law that the Defendants, Jon W. Dudas and the United States Patent and Trademark Office (collectively, "PTO"), violated the Administrative Procedure Act ("APA") in enacting the "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications" ("the Final Rules"), 72 Fed. Reg. 46,716 (Aug. 21, 2007) (attached hereto as Ex. 1).

This case is about elegantly simple laws that govern U.S. patents:

(i) In Article 1, Section 8, Clause 8 of the United States Constitution, Congress was granted the power to establish Patent Laws ("to promote the Progress of Science and useful arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

(ii) Congress exercised this power in 35 U.S.C. § 1 *et seq.*: 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. *Id.* §§ 102-03. To obtain a patent, an inventor must file a written application that contains a specification, an oath, and "one or more" claims. *Id.* § 112. And the PTO shall allow continuing applications and requests for continued examination at the request of an applicant. *Id.* §§ 120, 132.

(iii) Congress authorized the PTO to "establish regulations, not inconsistent with law" for a list of enumerated purposes. The relevant provisions of section 2(b)(2) authorize the PTO, through its Director, to "govern the conduct of proceedings in the Office," 35 U.S.C. § 2(b)(2)(A), and to "facilitate and expedite the processing of patent applications," 35 U.S.C. § 2(b)(2)(C).

The U.S. Constitution thus gave Congress, not the PTO, the power to establish the laws that govern the United States patent system. Congress has not authorized the PTO to limit an inventor's rights to a patent to reduce its backlog of pending applications. Nor has Congress authorized the PTO to limit those rights to reduce its general workload. Congress did not give the PTO any powers to enact substantive rules that affect or abridge patent rights. Congress did

not give the PTO the right to enact retroactive rules. And Congress did not give the PTO the right to limit the number of continuing applications, requests for continued examination ("RCEs"), or patent claims that an applicant may present. Since at least 2005, Congress has considered increasing the PTO's authority, and has even considered giving the PTO substantive rulemaking authority. But those proposals have not made any progress in Congress—not in 2005, not in 2006, and as 2007 comes to a close, not this year either. To date, Congress has never delegated to the PTO substantive rulemaking authority of any kind.

This case is about the fact that the PTO got tired of waiting for Congress to give it the power it wanted to reduce its workload and instead took matters into its own hands. In a blatant attempt to dispense with its backlog of patent applications, the PTO promulgated its own rules, the Final Rules, that will unambiguously terminate certain pending patent applications, prevent new applications, and effectively deny patent applicants the rights guaranteed to them by statute and controlling case law.

The PTO has gone too far. The Final Rules will harm not only GSK's interests, but also the public's interest in protecting human health and in promoting innovation. This cannot be tolerated by GSK, since the PTO's actions destroy the *quid pro quo* of already filed GSK patent applications, thereby putting at risk hundreds of millions of dollars of GSK capital, eviscerating business certainty for GSK, and destroying proprietary rights in GSK patent applications. Further, this cannot be tolerated by the millions of people awaiting cures for diseases they or their relatives or friends are suffering from or will in the future suffer from, which may be helped by inventions disclosed in GSK patent applications, but will never make it to market without strong patent rights.

The Final Rules stifle innovation. They would truncate not just GSK's rights, but the existing rights in more than 700,000 currently pending patent applications. The unparalleled outcry of opposition highlights the devastating repercussions of these rules. *Amici* representing the full breadth of industries, from information technology to biotechnology, and of all sizes, from individual inventors to multi-national corporations and organizations, have participated at the preliminary injunction stage and, now, at the summary judgment stage.

The public concern that the PTO has overstepped the legal framework created by Congress has been duly acknowledged on both sides of the political aisle. On October 25, 2007, Senior Democratic Senator Charles Schumer, a member of the Senate Judiciary Committee overseeing U.S. Patent Law Reform, wrote to Undersecretary Dudas at the PTO to request that he voluntarily stop the implementation of the Final Rules. Senator Schumer highlighted that because "there are questions as to whether the PTO has the necessary authority to limit the number of continuation applications," "the proposed rules may thus serve to undermine core principles of patenting process, [and] full candor to the PTO and the public." (Ex. 2.) Moreover, while he appreciated the PTO's "goal to create the most efficient and effective" patenting processes, in his view the proposed rules "may have the unintended consequences of stifling such innovation." (*Id.*)

Then, on November 15, 2007, from the other side of the political spectrum, Republican presidential candidate Mitt Romney commented: "With his preliminary injunction against the PTO, Judge Cacheris emphasized the importance of a dependable patent system to protect the significant investment capital of innovators. I applaud the decision." (Ex. 3.) Mr. Romney also said: "If I am privileged to serve as President of the United States, a tenet of my administration

will be to strengthen the U.S. patent system and immunize it from the type of anti-innovation governmental meddling duly enjoined by Judge Cacheris." (*Id.*)

II. OVERVIEW OF LEGAL DEFECTS IN THE FINAL RULES.

By enacting the Final Rules, the PTO has far exceeded its authority. The Final Rules are substantive rules contrary to the Patent Act and established case law, they are retroactive, and they run afoul of well-established constitutional doctrines. As the U.S. Court of Appeals for the Federal Circuit has recently reemphasized, "'an agency literally has no power to act . . . unless and until Congress confers power upon it.'" *Agro Dutch Indus. Ltd. v. United States*, --- F.3d ---, 2007 WL 4107570, at *7 (Fed. Cir. Nov. 20, 2007) (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Congress has never given the PTO substantive rulemaking authority. Congress has instead vested the PTO with limited procedural rulemaking authority to govern the conduct of proceedings in the PTO. The Final Rules are substantive in nature because they trump and expressly limit an applicant's statutorily defined rights to file continuing applications, RCEs, and patent claims. On the contrary, the relevant governing statutes and judicial pronouncements interpreting them do not limit an applicant's ability to file any number of continuing applications, RCEs, or claims.

Furthermore, not only has the PTO exceeded its authority in enacting the rules in the first place, but to make matters worse, the Final Rules apply retroactively to the backlog of more than 700,000 pending patent applications. Congress must ***expressly*** delegate authority to apply rules retroactively. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). Although Congress has never delegated to the PTO any such retroactive rulemaking authority, and the PTO does not dispute this lack of authority, the PTO has taken it upon itself to impose these new restrictions in mid-course on hundreds of thousands of pending applications.

In addition to exceeding the PTO's authority, the retroactive application of the rules to GSK's pending patent applications is an unconstitutional, *ultra vires*, and arbitrary and capricious taking of GSK's patent application property rights. GSK invests billions of dollars in research and development to create its inventions, which it initially holds as trade secrets. GSK surrenders its constitutionally protected trade secret rights as a *quid pro quo* for acquiring constitutionally protected rights in its patent applications. The parties' settled expectations are that the government will afford GSK strong, reliable patent protection in return for the publication of its trade secrets. In that bargained-for exchange, GSK maintains constitutional protection over its inventions by exchanging one form of property for another. The Final Rules, however, change GSK's *quid pro quo* with the government after it has already entered into that bargained-for exchange. The Final Rules, if applied retroactively, will destroy GSK's constitutionally protected property rights in its already filed patent applications, after GSK has already been induced under the current rules to disclose its trade secrets. These property rights, retroactively taken from GSK in violation of the Constitution, will be lost forever.

In addition to being beyond both the PTO's lack of substantive and retroactive rulemaking authority, the Final Rules also impose an incomprehensibly vague Examination Support Document ("ESD") requirement on applicants. The ESD requires that applicants perform a geographically, contextually, and financially boundless preexamination search (proposed 37 C.F.R. § 1.265(b)). The ESD's preexamination search is required if a patent application has more than five independent or more than twenty-five total claims. Conceding the vagueness of the ESD, the PTO directs applicants to other sources to clarify the details of what is required, like its Manual of Patent Examining Procedure ("MPEP"), for example. Notwithstanding that the MPEP and other published guidance fails to cure the vagueness of the

proposed regulation, the MPEP and other sources of extraneous support were not part of the rulemaking process, and were not published for notice and comment. Thus, the ESD requirement is both substantively and procedurally flawed.

Moreover, the Final Rules are procedurally flawed for another reason—they are not a logical outgrowth of the rules as originally proposed. For example, because the Final Rules' limit on the number of claims an applicant may seek is so different from the limit described earlier in the PTO's "Notice of Proposed Rulemaking," the agency was required to seek additional comments on the limits it adopted in the Final Rules. Yet the PTO did not even attempt to do so. Specifically, in its proposed rule, the PTO proposed limiting an applicant to the examination of ten "representative" claims before requiring the applicant to submit the onerous and vague ESD. The "representative" claims restriction limited an applicant to ***ten independent claims*** and, significantly, allowed an applicant to seek ***any total number of claims***. After receiving many negative comments regarding its proposed claims rule, the PTO issued the Final Rules, which impose an even more stringent limit of ***five independent claims and/or twenty-five total claims***. The drastic change from the proposed rule to the Final Rule is best highlighted by the fact that the PTO estimated that the proposed rule would have impacted only 1.2% of applications, whereas the claims limit of the Final Rules will potentially impact 23.7% of applications—an increase of more than 1800%. Interested parties could not have anticipated such a change in the rules and, as a result, the Defendants again violated their notice and comment obligations under the APA. Thus, for this additional reason, the Final Rules are procedurally defective.

Finally, the Final Rules are *per se* arbitrary and capricious because the PTO exceeded its statutory authority in promulgating these rules and because the principal justification for the

Final Rules (reduction of workload) has not been adequately or rationally explained. Therefore, the Final Rules are unsupported.

For at least the foregoing reasons, as explained in more detail below, GSK respectfully requests that the Court enter judgment as a matter of law that the Final Rules are invalid, vacate the Final Rules, and grant a permanent injunction against their enforcement.

III. STATEMENT OF UNDISPUTED FACTS.

A. GSK Spends Up To One Billion Dollars Or More Researching And Developing A New Drug.

1. "GSK is the second largest pharmaceutical company in the world." (Decl. of Sherry M. Knowles in Supp. of Pls.' Mot. for TRO and Prelim. Inj. (hereinafter, "Knowles Decl."), ¶ 6) (attached hereto as Exhibit 4 without exhibits thereto.) "GSK researches, develops, tests, and markets life-saving medicines that treat some of the worst human diseases, including cancer, cardiovascular disease, respiratory diseases such as asthma and chronic obstructive pulmonary disease, HIV, and depression." (*Id.* ¶ 7.)

2. "GSK's drug research [necessarily] requires a large, up-front, totally at-risk investment." (*Id.* ¶ 9.) That research involves sophisticated, high-level sciences, including organic chemistry and molecular biology, which require significant resources to generate innovative drugs. (Verified Am. Compl., Dkt. No. 5 in 1:07cv1008, ¶ 32.) "In 2006, GSK invested $6.4 billion, or approximately $18 million per day, on drug research and development." (Knowles Decl. ¶ 12.) GSK's discovery of a new drug and the development work required for market introduction can take ten years or more of hard work and up to a billion dollars or more in investment. (Verified Am. Compl. ¶¶ 52, 54.)

B. GSK Relies On Strong Patent Protection To Recoup Its Significant Investments.

3. GSK's drug products protect and support the health and life of American citizens. (*Id.* ¶ 32.) GSK has expended tremendous research investments to bring those drugs to market. (*Id.*) The current patent laws encourage GSK to invest in the discovery and development of those drugs, as well as new drugs currently under development, by providing robust patent protection. (*Id.*)

4. Under the current patent system and its predictable bases for rational business decisions and investment, GSK has brought to market some of the leading drugs in the world, including (just to mention a few) Advair and Veramist (respiratory problems), Epivir, Combivir, Epzicom and Trizivir (HIV), Valtrex (herpes), Avodart (enlarged prostate), Zofran (chemotherapy induced nausea), and Tykerb (breast cancer), as well as a host of vaccines such as Infanrix (pediatric multiple protection), Rotarix (rotavirus), Engerix-B (hepatitis B), and, in final development, Cervarix (cervical cancer), and a pandemic avian flu vaccine. (Knowles Decl. ¶ 16.) The current patent system is important to GSK for recovering the significant costs of development and regulatory approval associated with these and other critical drugs. (*Id.* ¶ 17.)

5. In filing patent applications in the PTO, GSK has relied on the statutory framework that allows it to file any number of continuations, any number of RCEs, and any number of claims. (*Id.* ¶¶ 17-19; *see* Decl. of Harry F. Manbeck, Jr., In Supp. of GSK's Mot. for Summ. J. (hereinafter, "Manbeck Decl.", attached hereto as Exhibit 5) ¶¶ 27-28, 32-34, 38, 45-46.)

6. Without strong patent protection, a new drug would be copied and sold by others who have not incurred the billions of dollars in research investments borne by an innovator company like GSK. (Knowles Decl. ¶ 14.) "Without patent protection or with inadequate

protection, GSK would not be unable to undertake the huge investments in research and development necessary to bring drugs—including drugs that treat the most serious and life-threatening diseases—into widespread use." (*Id.* ¶ 15.)

C. The Current Status Of Some Of GSK's Pending Patent Applications.

7. Presently, GSK has over 1900 patent applications pending. GSK has more than 100 pending applications in which two or more continuing applications have been filed. GSK also has approximately 30 or more pending applications in which two or more continuing applications and a RCE have been filed. (*Id*. ¶¶ 18, 20.) Thus, many of GSK's pending patent applications are already over the limits imposed in the Final Rules.

IV. IMPORTANCE OF PRIORITY DATE TO PATENT APPLICATIONS.

The date of filing of each patent application is critically important. The applicant's entitlement to a patent, *e.g.*, novelty under 35 U.S.C. § 102 and non-obviousness under 35 U.S.C. § 103, is judged from the earliest filing date to which the application is entitled ("the priority date"). The priority 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). (Manbeck Decl. ¶¶ 14-15; Verified Am. Compl. ¶ 37.) If the priority 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. (Manbeck Decl. ¶¶ 15, 18.) In such situations, if the earlier-filed application is published as is often the case under 35 U.S.C. § 122, then the earlier-filed application itself may become prior art against the later-filed application. (*Id.* ¶ 19.) The priority date is also critical to GSK because, by obtaining the earliest possible

filing date, GSK may establish that its patent application was filed before a similar application filed by someone else. (*Id.* ¶ 14.)

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. (Verified Am. Compl. ¶ 38.) 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. (*Id.*) 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) ("*Symbol IV*") (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. (Verified Am. Compl. ¶ 38.) 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. (Ex. 1 at 46,772-77.) 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 IV*, 422 F.3d at 1385.

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. (Verified Am. Compl. ¶ 39.) 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. (Ex. 1 at 46,773-74.)

After a long and difficult research process, GSK typically files patent applications on a discovered potential class of new drug products, well before commencing human clinical trials. (Knowles Decl. ¶ 18.) The potential class of compounds (a "genus") will include numerous structurally related compounds ("species"), which are all possibilities for drug development and sale. At the time GSK files its initial applications, GSK may have little idea which member of the drug class genus will ultimately be brought to market until years later after the lengthy regulatory procedures have run their course. (*Id.* ¶ 19.) Accordingly, GSK often files applications containing a disclosure encompassing the related group of potential "lead drug" candidates (the "genus"), understanding that it will prosecute one of the drugs in the genus in continuing applications, as its depth of knowledge of the properties of the genus and of commercial realities grows through the development and regulatory processes. (*Id.*) For example, if the selected drug fails in expensive clinical trials, an alternative can be selected, and continuing patent applications filed to protect the new lead drug candidate.

In a typical GSK patent application on a new class of chemical compounds, the disclosure includes a number of inventions. One example of such a GSK application is described in the Knowles Declaration and pertains to compounds for the treatment of the inflammatory

component of certain diseases, including asthma and atherosclerosis. (*Id.* ¶¶ 23-29.) The PTO has already issued one patent in this family, U.S. Patent No. 7,235,551 ("the '551 patent"), for part of the disclosed inventive subject matter (demonstrating patentability). (*See id.* ¶ 24.) But the '551 patent discloses more than it claims. It discloses:

(i) Chemical formulas that describe variations of the class (*see, e.g.*, Formulas (I), (Ia), (II), (IIa), (III), (IIIa), (IV), (IVa), (V), (Va) in Cols. 4-8 of the '551 patent) (sometimes referred to as "genuses" of compounds);

(ii) Numerous subsets of the broad genuses of (i) which highlight preferred embodiments of the invention (*see, e.g.*, Col. 9, line 10 to Col. 22, line 32) (sometimes referred to as "subgenuses" of compounds);

(iii) Specific examples of compounds within the class (*see, e.g.*, Col. 24, lines 1-31, and Tables 1-7) (in this case over 160 specific compounds, sometimes referred to as "species");

(iv) Processes for the manufacture of the compounds (*see, e.g.*, Col. 24, line 32 to Col. 30, line 21);

(v) Methods of treatment of human diseases with the disclosed compounds (*see, e.g.*, Col. 30, line 23 to Col. 44, line 15); and

(vi) Pharmaceutically acceptable salts of the disclosed compounds (*see* Col. 22, lines 55-62).

(*Id.* ¶ 34.) Under current U.S. patent law, GSK typically presents and prosecutes a portion of this subject matter at a time, each in its own separate application, all of which get the benefit of the filing date of the first patent application that was filed (*i.e.*, the priority date). (*See* Knowles Decl. ¶¶ 18-19.) It is critical that all of these continuing patent applications that present additional portions of the pharmaceutical inventions get the benefit of the critical "stake in the ground" so as not to unfairly lose patentability.

V. STATUTORY AND REGULATORY BACKGROUND.

A. The PTO's Proposed Rules.

In January 2006, the PTO issued two separate notices of proposed rule making in the Federal Register. The first Notice of Proposed Rule Making is entitled "Changes To Practice for

Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims." 71 Fed. Reg. 48 (Jan. 3, 2006) ("NPRM 1"). (Ex. 6.) The second Notice of Proposed Rule Making is entitled "Changes to Practice for the Examination of Claims in Patent Applications." 71 Fed. Reg. 61 (Jan. 3, 2006) ("NPRM 2"). (Ex. 7.)

In NPRM 1, the PTO proposed limiting applicants to a single continuing application before requiring that the applicant submit a petition "showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application." (Ex. 6 at 59-60 (Proposed Rule 78(d)).) The PTO also proposed limiting applicants to a "single request for continued examination," before requiring applicants seeking further RCEs to file a petition "showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application." (*Id*. at 61 (Proposed Rule 114).)

In relevant part, NPRM 2 proposed amending the PTO's rules to allow an applicant to obtain examination of only claims designated by the applicant as "representative claims." (Ex. 7 at 62.) Each independent claim automatically counted as a "representative" claim. (*See id*.) If the applicant chose to submit more than ten independent claims or designate a combination of more than ten independent and dependent claims, then the applicant would have to provide an ESD. (*See id*. at 67-68 (Proposed Rule 75).) The PTO also proposed adding Rule 261 to the Patent Office rules setting forth the requirements of the ESD, which would include, for example, a preexamination search, an information disclosure statement citing the reference or references deemed most closely related to the subject matter of each designated claim, and, for each claim

cited, identification of all limitations of the designated claims found in the reference or references. (*See id*. at 68-69.)

Numerous entities, including GSK, submitted comments to the proposed rules, both critiquing the substance of the proposed rules and offering constructive alternatives. (*See, e.g.*, Exs. 8-15.) The general tenor of the more than five hundred comments submitted was almost uniformly negative. GSK, and many others, commented that the proposed rules would damage their business and stifle innovation. (*See* Ex. 8; Ex. 9; Ex. 10 at A02664-65; Ex. 11) GSK and others also commented that the proposed rules were beyond the PTO's statutory authority. (*See, e.g.*, Ex. 8 at A02373-76; Ex. 14 at A02834-48.) Despite the overwhelmingly negative commentary, the PTO marched forward.

B. The PTO's Final Rules.

1. The Final Rules Arbitrarily And Mechanically Limit Patent Applicants To Only Two Continuing Applications Without A Petition And Showing.

The Final Rules impose an arbitrary and mechanical limit on continuing applications. Applicants may file no more than two nonprovisional continuing applications as of right. After that, an applicant must file a petition showing that the "amendment, arguments, or evidence ***could not have been*** submitted during the prosecution of the prior-filed application." (*See* Ex. 1 at 46,839 (Final Rule 78).) For a particular continuing application, if the applicant cannot satisfy the "could not have been submitted" showing, it will lose the benefit of priority to which it was otherwise entitled under 35 U.S.C. §§ 120, 121, or 365(c).

The "could not have been submitted" standard is tantamount to a "physical impossibility" standard, which contradicts the current law and precludes an applicant in almost all circumstances from being granted a petition for a third continuing application. (Manbeck Decl. ¶ 41.) Indeed, in responding to comments, the PTO confirmed that it would consider almost all

circumstances to be insufficient under that standard. (*See* Ex. 1 at 46,772-77 (responses to Comments 80 through 100); *see also* Verified Am. Compl. ¶ 40.) Further, the "could not have been submitted" standard places GSK in the untenable position of either averring that it physically could not have presented an amendment before (thus risking a violation of its ethical obligations to the PTO under 37 C.F.R. § 10.85) or not filing a petition and losing its right to prosecute additional patent claims on its inventions. (*See* Knowles Decl. ¶¶ 40-44; Manbeck Decl. ¶ 42.) Exacerbating the negative impact of these new continuing application rules is the fact that the PTO will apply the new restrictions retroactively. (Ex. 1 at 46,716-17; Manbeck Decl. ¶ 39.)

2. The Final Rules Arbitrarily And Mechanically Limit Patent Applicants To One RCE Without A Petition And Showing.

The Final Rules also include an arbitrary and mechanical rule restricting an applicant to one RCE in a patent family before requiring that the applicant file 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 . . . ." (Ex. 1 at 46,841 (Final Rule 114) (emphasis added).) The petition and showing requirement for RCEs suffers from the same shortcomings as the petition and showing requirement for continuing applications. (Manbeck Decl. ¶¶ 40-42.) Likewise, the new limitation on RCEs also applies retroactively by requiring a petition and showing if an applicant files an RCE after November 1, 2007, after having filed an RCE in an earlier-filed application in the same family before November 1, 2007. (Ex. 1 at 46,717; Manbeck Decl. ¶ 29.)

3. The Final Rules Arbitrarily And Mechanically Limit The Number Of Claims An Applicant May Prosecute.

The Final Rules also arbitrarily and mechanically limit the number of claims an applicant may seek. Specifically, Final Rule 75 limits applicants to five independent claims and a total of

twenty-five claims ("the 5/25 limit") before requiring that applicants file an ESD. (*See* Ex. 1 at 46,836-37 (Final Rule 75).) The ESD imposes incomprehensibly vague and extreme requirements on applicants, including a requirement that applicants perform a seemingly boundless preexamination search, off-loading the PTO's assigned duties onto applicants, with little or no guidance on what would be sufficient. (*Id.* at 46,842 (Final Rule 265(b)); Manbeck Decl. ¶¶ 48-49.) For example, Final Rule 265 does not specify whether the applicant must search electronically, manually, or both; which countries must be searched; what databases must be searched; or which libraries must be searched. (Manbeck Decl. ¶ 49.) And there is no cost cap on searching. (*Id.*) The ESD requirements are retroactive because they apply to any pending application that has not yet received a First Office Action from the PTO on the merits. (Ex. 1 at 46,716; Manbeck Decl. ¶ 52.)

VI. LEGAL STANDARD FOR SUMMARY JUDGMENT.

GSK has brought this case under the APA to challenge the validity of the Final Rules. In a case brought against the PTO under the APA, the ordinary standard for summary judgment applies. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005).[1] That standard is well-settled: Summary judgment "should be rendered" if the moving party has shown "that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Conroy v. Reebok Int'l, Ltd.*, 14 F.3d 1570, 1575 (Fed. Cir. 1994) (quoting prior version of Fed. R. Civ. P. 56(c)). Thus, GSK must show, as a matter of law, that an "agency action" of the PTO is '"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Star Fruits*, 393 F.3d at 1281

[1] Cases challenging the PTO's authority under the APA to issue substantive regulations relating to the patent laws raise substantial questions under the patent laws; accordingly, appellate jurisdiction lies in the U.S. Court of Appeals for the Federal Circuit, whose law governs the standard applied at summary judgment. *Star Fruits*, 393 F.3d at 1281.

(quoting 5 U.S.C. § 706(2)). GSK is entitled to judgment as a matter of law because the PTO's actions are defective in each of these respects. Moreover, in addition to their substantive defects, GSK is also entitled to summary judgment as the PTO's promulgation of the Final Rules violated the APA-required notice and comment rulemaking process. *See, e.g., Nat'l Ass'n of Mfrs. v. Dep't of Labor*, 159 F.3d 597, 598-99 (D.C. Cir. 1998) (noting that the District Court had issued summary judgment against an agency that failed to follow notice-and-comment processes).

VII. GSK IS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON ALL CAUSES OF ACTION.

A. The PTO Lacks Substantive Rulemaking Authority, Cannot Promulgate Rules Inconsistent With Established Law, And Is Entitled To No Deference When It Attempts To Do So.

There is no dispute that the PTO lacks "any general substantive rulemaking power." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996); *see also Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003). In fact, the PTO concedes that it lacks any substantive rulemaking authority. (*See* Defs.' Opp. to Pls.' Mot. TRO and Prelim. Inj., Dkt. No. 46 in 1:07cv1008, 21-23.) Thus, the PTO cannot promulgate substantive rules, *i.e.*, rules that "effect[] a change in existing law or policy which affect[] individual rights and obligations." *Animal Legal Def. Fund. v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (citations and internal quotations omitted). Here, rather than substantive rulemaking authority, in 35 U.S.C. § 2(b)(2), Congress has granted the PTO only limited rulemaking authority. That section authorizes the PTO to "establish regulations, not inconsistent with law" for a list of enumerated purposes, such as, to "govern the conduct of proceedings in the Office," 35 U.S.C. § 2(b)(2)(A), and to "facilitate and expedite the processing of patent applications," *id.* § 2(b)(2)(C).

The PTO's lack of substantive rulemaking authority is further evidenced by the fact that since 2005, Congress has considered giving the PTO such authority, but has never done so. (*See* Manbeck Decl. ¶ 9.) For example, in 2005, the U.S. House of Representatives considered vesting the PTO with substantive authority to limit continuing applications, but the resolution did not pass. *See* H.R. 2795, 109th Cong. § 123 (June 8, 2005) ("The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application . . . ."). In 2006, Congress again declined to grant such authority. *See* S. 3818, 109th Cong., § 9 (2006). And, as of the end of 2007, Congress still has not granted such substantive authority to the PTO. (*See* Manbeck Decl. ¶ 9; *compare* Ex. 16, § 11 (Senate Bill 1145 as introduced), with Ex. 17 (Section 11 is no longer included in the "Senate Manager's" version .).)

In *Adams Fruit Co. v. Barrett*, the Supreme Court held that agencies that lack authority to regulate in particular areas gain ***no deference*** to their interpretations of law in those areas. 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."). It is not enough for an agency to possess a power to issue regulations over ***some aspects*** of a statute's coverage. As the Court explained in *Adams Fruit*:

> Congress clearly envisioned, indeed expressly mandated, a role for the Department of Labor in administering the [Agricultural Worker Protection Act ("AWPA")] statute by requiring the Secretary to promulgate standards implementing AWPA's motor vehicle provisions. This delegation, however, does not empower the Secretary to regulate the scope of the judicial power vested by the statute. Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental "that ***an agency may not bootstrap itself into an area in which it has no jurisdiction***."

Id. at 650 (emphasis added) (citation omitted). In such circumstances, *Chevron* deference is inapplicable. *See A.T. Massey Coal Co. v. Holland*, 472 F.3d 148, 167 (4th Cir. 2006)

(according no deference to Social Security Administration where Congress did not delegate the authority to interpret the provisions of the Coal Act).

Here, Congress has not granted the PTO authority to promulgate substantive rules interpreting the patent laws. (*See* Manbeck Decl. ¶ 9.) On the contrary, in the Federal Courts Improvement Act of 1982, Congress centralized construction and interpretation of the patent laws in the U.S. Court of Appeals for the Federal Circuit. *See In re Lueders*, 111 F.3d 1569, 1577 (Fed. Cir. 1997) ("[T]he Federal Courts Improvement Act was a significant venture . . . . [It] consolidated in this court, the Court of Appeals for the Federal Circuit (CAFC), nationwide jurisdiction over all appeals from patent cases in the district courts in addition to the CCPA's existing jurisdiction over direct appeals from the PTO boards."). Because the PTO exceeded its statutory authority when it promulgated substantive rules interpreting the patent laws—the exclusive province of Congress and the Federal Circuit—the PTO is not entitled to any deference. *See, e.g.*, *Fabil Mfg. Co. v. United States*, 237 F.3d 1335, 1341 (Fed. Cir. 2001) (agency could not claim deference over matter delegated to the judiciary for resolution).

As Congress drafted them, the patent laws do not limit the number of continuing applications, RCEs, or claims that an applicant may file. (*See* Manbeck Decl. ¶¶ 28, 38, 46.) Congress has not vested the PTO Director with the authority or discretion to limit those statutes; nor has Congress granted the Director the authority to impose retroactive limitations. Rather, Congress has only vested the Director with narrowly defined powers to facilitate the granting of applications that satisfy the conditions for patentability outlined in those statutes. Contrary to these clear limits to its delegated power that the PTO has long observed, the current PTO apparently interprets its power under 35 U.S.C. § 2(b)(2)(C) to "facilitate and expedite the processing of patent applications" to allow it to redefine the statutory rules concerning

continuing applications, RCEs, and claims. Neither by its plain terms nor by implication does this application-processing power delegate substantive rulemaking power to the PTO. Because "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001). In terms pure and simple, the PTO wholly lacks substantive rulemaking authority to interpret the terms of the patent laws and its attempt to alter patent rights is therefore *ultra vires*, unconstitutional, and entitled to no deference.

B. The Arbitrary And Mechanical Limit On Continuing Applications In Final Rule 78 Is Contrary To Established Patent Law.

Final Rule 78 restricts an applicant to two continuing applications before requiring a petition and showing. (Ex. 1 at 46,839.) Nothing in section 120 of the patent laws, however, limits the number of continuation applications an applicant may file.[2] *See* 35 U.S.C. § 120. Rather, it expressly states that a continuation application "shall" be given the benefit of the same filing date as the application to which it references, so long as the other requirements of Title 35 are satisfied:

> ***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, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application ***shall have the***

[2] The right to file continuing applications dates back to at least 1863 when the Supreme Court recognized that the Patent Act allowed an applicant to file continuing patent applications. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863). In the ensuing years, the case law further clarified that the patent laws did not limit the number of continuing applications that an applicant could file. *See, e.g.*, 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 581, at 204 ("It 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."). Congress codified this law when it enacted section 120 in 1952. *See* S. Rep. No. 1979, at 2413 (1952) (accompanying H.R. 7794). As enacted in 1952, section 120 stated that a continuation application "shall" be entitled to the benefit of an earlier-filed application, provided the application met certain formal requirements. Act of July 19, 1952, Pub. L. No. 593-950, 66 Stat. 792, 800 (1952). Congress has amended section 120 only minimally since then.

> ***same effect,*** as to such invention, as though filed on the date of the prior application . . . .

35 U.S.C. § 120 (emphasis added). Thus, Final Rule 78's numerical limit on continuing applications exceeds the plain language of section 120. (*See* Manbeck Decl. ¶ 38.)

This is not the first time that the PTO has attempted to impermissibly restrict continuing applications. Courts have rejected these prior attempts as contrary to the language of section 120. *See, e.g.*, *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (holding that there "is no statutory basis for fixing an arbitrary limit to the number of prior applications . . . "); *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977) ("[L]imit[ing] . . . applications is a matter of policy for the Congress . . . ."); *Ex parte Hull*, 191 U.S.P.Q. 157, 159-60 (Pat. & Tr. Office Bd. App. 1975) (The PTO Board of Appeals conceded that the PTO lacks such power.). As with its prior attempts at limiting continuing applications, the PTO's present attempt should similarly be rejected.

The PTO tries to circumvent this binding adverse authority by arguing that the Final Rules impose only "reasonable limits" on continuing applications. (*See* Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 25-26.) However, the PTO is imposing a hard limit, as it has made clear that it will deny a petition for a third continuing application in almost all circumstances. (*See* Ex. 1 at 46,769-77.) Indeed, the PTO has even indicated that it will refuse to accept justifications that the Federal Circuit expressly endorsed in *Symbol IV*. *See id.* at 1385; (*See* Manbeck Decl. ¶¶ 32-35, 38.) Given the PTO's reason for promulgating Final Rule 78—limiting continuing applications to reduce its workload—the PTO's unwillingness to entertain proper continuing applications is not surprising. (*See, e.g.*, Hrg. Tr., Dkt No. 61 in 1:07cv1008, at 51:5-11 (conceding that the goal is "stopping" continuations); Ex. 18 at A00432 ("Why Limit Continuations?").)

Further evidence that the PTO is imposing a hard limit is the fact that the "could not have" evidentiary burden will preclude the actual filing of the petition itself in almost all cases. (*See* Ex. 1 at 46,767-79.) PTO Rule 10.85(a)(5) bars a practitioner from knowingly making a false statement of law or fact. 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 earlier—GSK's attorneys would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition arguing that the amendment, evidence, or argument could not have been submitted earlier. (Manbeck Decl. ¶ 41.) 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. (*Id.* ¶ 42.) As a result, the PTO's petition and showing requirement represents a false choice and is a *de facto* limit on continuing applications.

The PTO asserts that two Federal Circuit cases applying "prosecution laches" establish its authority to impose "reasonable limits" on continuing applications. (*See* Defs.' Opp. Pls. Mot. TRO and Prelim. Inj. 25-26.) In making this argument, however, the PTO misconstrues the cases upon which it purports to rely. While the PTO may reject applications on a case-by-case basis under the equitable doctrine of prosecution laches where applicants egregiously abuse the application process, *see In re Bogese II*, 303 F.3d 1362, 1368 (Fed. Cir. 2002), *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1364-65 (Fed. Cir. 2002) ("*Symbol II*"), it may not deny continuing applications using the mechanical bright line of the Final Rules. Nothing in *Bogese II* or *Symbol II* suggests such authority. On the contrary, the Federal Circuit has already made clear that the PTO lacks the ability to impose "a mechanical

rule based on a misconstruction of the statutory requirements." *Bogese II*, 303 F.3d at 1368 n.6. Yet in the Final Rules, the PTO has imposed precisely such a mechanical limitation.

The PTO's power is limited to ***applying*** the judicial doctrine of prosecution laches on a case-by-case basis (so long as it does not abuse its discretion in so doing). (*See* Manbeck Decl. ¶ 38.) That doctrine does not grant the PTO the authority to adopt broad mechanical rules. The factual underpinnings of the *Symbol*[3] and *Bogese* cases show that the PTO's authority to regulate the filing of continuing applications is limited to rejecting claims on a case-by-case basis in light of the doctrine of prosecution laches—a doctrine to be invoked "sparingly lest statutory provisions be unjustifiably vitiated" and "applied only in egregious cases." *Symbol IV*, 422 F.3d at 1385-86 (affirming the unenforceability of fourteen patents under the doctrine of prosecution laches when "an 18- to 39-year time period had elapsed between the filing and issuance of the patents in suit"); *see also In re Bogese II*, 303 F.3d at 1369 (affirming a PTO rejection where "Bogese filed twelve continuation applications over an eight-year period and did not substantively advance prosecution of his application when required and given an opportunity to do so by the PTO"). Thus, contrary to the PTO's contention, these cases do not authorize the PTO to rewrite or extend the judicial doctrine of laches by issuing rules that arbitrarily bar applicants from filing more than two continuing applications.

C. The Arbitrary And Mechanical Limit On RCEs In Final Rule 114 Is Contrary To Established Patent Law.

The PTO has also exceeded its authority by promulgating Final Rule 114, which limits a patent applicant to one RCE per patent application family. (Ex. 19 at A00264 (stating that the rule "[l]imits the number of . . . RCEs that may be filed by right"); Ex. 18 at A00433 (stating that

[3] *Symbol II* merely found that section 120 did not abrogate the doctrine of prosecution laches. *Symbol IV* involved the application of the doctrine to the facts of the case.

the rule "[l]imits . . . RCEs").) As aptly stated by Senator Schumer (who is on the Judiciary Committee and actually involved in Congress's patent reform efforts) in his letter to the PTO:

> With respect to the rule on continuing applications, under the current rules, there is effectively no limit on the number of continuation applications—or requests for continuation applications—that a prospective patent holder could file. The pending rule change would limit the number of continuations and requests for continued examination without a showing by the petitioner. Concerns have been raised as to the impact this proposed rule will have on certain types of inventions. In addition, there are questions as to whether the PTO has the necessary authority to limit the number of continuation applications. (Ex. 2.)

Contrary to Final Rule 114, section 132(b) of the Patent Act provides that the Director must continue examining the application at the applicant's request: "The Director ***shall*** prescribe regulations to provide for the continued examination of applications for patent ***at the request of the applicant***." 35 U.S.C. § 132(b) (emphasis added.) In using the word "shall" and the phrase "at the request of the applicant," Congress manifested its intent that RCEs be unlimited, with invocation of that procedure being committed to the discretion of the applicant, not the PTO. (*See* Manbeck Decl. ¶¶ 27-28.) This interpretation is further bolstered by Congress's pronouncement upon enacting section 132(b) that the RCE provisions of section 132(b) apply to "all applications" filed after June 8, 1995, not just one application per patent application family. American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 (1999).

When the PTO initially enacted regulations to provide for RCEs under section 132(b), it too recognized that the statute did not limit the number of RCEs an applicant may file. Specifically, the PTO recognized that the new RCE provisions of section 132(b) applied to "all applications" and that "an applicant . . . is not limited in the number of times" he can file an RCE. *See* Request for Continued Examination Practice and Changes to Provisional Application Practice, 65 Fed. Reg. 50,092, 50,095 (Aug. 16, 2000); *see also* Changes to Application

Examination and Provisional Application Practice, 65 Fed. Reg. 14,865, 14,868 (Mar. 20, 2000) (interim rule).

Now, just a few years later, and with the express goal to address its application backlog, the PTO has changed its mind about what the law requires, has bypassed Congress, and has sought to mechanically limit an applicant's right to file RCEs to a single opportunity per application family. In so doing, the PTO has clearly exceeded its authority.

D. The Arbitrary And Mechanical Limit On The Number Of Claims An Applicant May File In Final Rule 75 Is Contrary To Established Patent Law.

The PTO itself has conceded that Final Rule 75 limits the number of claims that an applicant may seek. (*See, e.g.*, Ex. 18 at A00434 ("Why Limit Claims?"); Ex. 20 at A07096 ("Plus Claims & Continuation Limits"); Ex. 21 at A07200 (same); Ex. 22 at A03764 (discussing goals "contingent upon the implementation of the final rules package on claim limitations"); Ex. 23 at A08284, A08296 (conceding that applicants will file a number of claims under the 5/25 limit "to avoid having to prepare an ESD").)

As the PTO has also conceded, "[t]he patent statute and rules of practice ***do not limit*** the number of claims (independent or dependent) that may be presented in an application." (Ex. 24 at A07333.) Rather, the Patent Act provides an inventor with a statutory right to a patent unless the claimed invention is not new or is obvious. 35 U.S.C. §§ 102, 103. To obtain a patent, an inventor must file a written application that contains a specification ending in one or more claims. *Id.* §§ 111, 112. The law also requires that the claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." *Id.* § 112, ¶ 2. These provisions embody the only statutory restrictions on claim presentation. (Manbeck Decl. ¶¶ 43-44.)

Beyond these restrictions, it is well established that an applicant possesses the right to express an invention in the necessary or desired number and form of claims. *See In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims."); *In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."); *In re Clark*, 97 F.2d 628, 631 (C.C.P.A. 1938) ("As we understand it, under the patent law and the prevailing Patent Office practice, an inventor, where it is difficult to express his invention in the form of claims, has the right to, and ordinarily for his own protection does, express the same invention in more than one claim. If by so doing he more clearly defines his invention and does not by undue multiplicity obscure the same, he is acting within the rights granted and the duties required by the patent laws."). Hence, nothing in the Patent Act authorizes the PTO to impose mechanical or arbitrary rules limiting the number of claims an application may seek.

The PTO has previously attempted to impose limits on the number of claims an applicant could file in a single application. For instance, in *In re Wakefield*, the PTO attempted to limit the number of claims an applicant could obtain in a single application by rejecting all of the forty pending claims for undue multiplicity under 35 U.S.C. § 112, ¶ 2. 422 F.2d at 900. Because the PTO concluded that the number of claims was unreasonably large, it required the applicant to reduce the number of claims to fifteen. *Id.* The court disagreed, finding that the PTO lacked statutory authority to reject the claims as being "unnecessary." *Id.* at 900-01. As the Court explained:

> It is rarely possible to determine necessity for narrower claims at the time of prosecution. An applicant often does not know all the prior art that may be

> asserted against his broader claims when he litigates his patent. Further, he is never sure that the broader claims will not be successfully attacked on other grounds when litigated in the courts.
>
> * * *
>
> Moreover, there is no statutory authority for rejecting claims as being 'unnecessary.' For these reasons, ***an applicant should be allowed to determine the necessary number and scope of his claims***, provided he pays the required fees and otherwise complies with the statute.[4]

Id. (citations omitted) (emphasis added); *see also In re Flint*, 411 F.2d 1353, 1356-57 (C.C.P.A. 1969) (rejecting the PTO's attempt to limit an applicant to 15 claims under the doctrine of undue multiplicity because 42 claims is an unreasonable number for a relatively simple invention). Further, in rebuffing the PTO's attempts to limit the number of claims, the courts have required that the PTO evaluate applications on a case-by-case basis. *See, e.g., In re Flint*, 411 F.2d at 1357 (requiring that the PTO assess the propriety of the number of claims "on the basis of the relevant facts and circumstances in each individual case") (quoting *In re Chandler*, 319 F.2d at 225); PTO, MPEP § 2173.05(m) (8th ed. 2005) ("Undue multiplicity rejections based on 35 U.S.C. 112, second paragraph, should be applied judiciously and should be rare.").

In short, Final Rule 75 is contrary to the Patent Act and established case law. The PTO has no authority, statutory or otherwise, to impose mechanical rules that set arbitrary claim

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[4] In 35 U.S.C. § 41, Congress sets forth the fees that the PTO may charge an applicant. More specifically, section 41(a)(1)(B) requires the Director to charge an applicant $78 per independent claim greater than three and $18 per claim greater than twenty. Thus, as is clear from the structure of the statute, Congress has determined that applicants be permitted to file any number of claims provided that the applicant pays the fee and that the claims otherwise comply with the statutory provisions of the patent laws. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984) (*Chevron* step one analysis is to be informed by the "traditional tools of statutory construction."); *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 558 (2005) ("[W]e must examine the statute's text in light of context, ***structure***, and related statutory provisions.") (emphasis added).

limits. Congress has established the applicable limits and the Courts are empowered to interpret those limits. The PTO may not promulgate rules to the contrary.

E. The ESD's Preexamination Search Requirement Is Incomprehensibly Vague And Fails To Provide Sufficient Notice As To How To Comply.

Under Final Rule 75, if a patent application exceeds the 5/25 claim limit, then the applicant must file an ESD in compliance with Final Rule 265. (Ex. 1 at 46,836.) Final Rule 265(b) sets forth the ESD requirements, including the requirement that the applicant perform a preexamination search. (*Id*. at 46,842.) The preexamination search requires an applicant to search "U.S. patents and patent application publications, foreign patent documents and non-patent literature." (*Id*.) Neither the rule nor the PTO's responses to comments in the Final Rules, however, provide any boundaries on the scope of the search and, as a result, GSK cannot comply with this regulation. (Manbeck Decl. ¶ 49); *see also United States v. Lanier*, 520 U.S. 259, 266 (1997) (A regulation is vague when it "either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application . . . ."). For instance, the rule does not indicate whether the applicant must conduct electronic searches, manual searches, or both; in which countries' databases the applicant must search; or in which libraries the applicant must search. (Manbeck Decl. ¶ 49.) Certainly, the cost of searching could be quite large, and the rule does not set forth an expense cap or limitation. (*Id.*)

Patent applicants would not know how to comply with the ESD preexamination search requirement. (*See id.*) Read literally, the ESD requirement demands that applicants search the patent literature of the entire world, as well as unspecified "non-patent literature," without regard to cost. (*See id.*) Indeed, the PTO's own Patent Public Advisory Committee recognized that

"[t]here is no rule of reason applied to foreign patent searching and non-patent literature searching." (Ex. 25 at A01295.)

The PTO attempts to ward off the vagueness challenge by claiming that its MPEP and the instructions provided therein provide the necessary clarity or narrowing. (Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 36-37; Ex. 1 at 46,800.) This reliance is misguided, however, as the MPEP does not give clear instructions that, if obeyed, guarantee the patent applicant that it is in compliance with Final Rule 265. In fact, in response to comments on the boundless nature of the preexamination search, the PTO merely indicated that "[i]f applicant follows the search guidelines set forth in the MPEP, then the preexamination search ***should*** be sufficient." (Ex. 1 at 46,800 (emphasis added).) Moreover, the PTO's reliance on the MPEP is unavailing in any case because the MPEP may not be used in that fashion, because that manual is not itself law. (Manbeck Decl. ¶ 50.) Indeed, the PTO concedes this in the MPEP itself: "The [MPEP] does not have the force of law or the force of the rules in Title 37 of the [C.F.R.]." PTO, Foreword to MPEP (8th ed. 2005).

Even without the PTO's concession, independent legal principles would prevent treating the MPEP as law because an agency pronouncement that regulates private parties must go through notice and comment. *See* 5 U.S.C. §§ 553(b)-(c). Notably, the PTO has never subjected the MPEP to notice and comment. Thus, the PTO may only use the MPEP as guidance for internal procedure, *see* 5 U.S.C. § 553(b)(B); *Nathan Katz Realty, LLC v. NLRB*, 251 F.3d 981, 988 (D.C. Cir. 2001) (finding that rules of "internal procedure" would not be subject to notice and comment). It may not use such a document to regulate the conduct of private parties. *See CropLife Am. v. EPA*, 329 F.3d 876, 881-82 (D.C. Cir. 2003); *Gen. Elec. Co. v. EPA*, 290 F.3d

377, 385 (D.C. Cir. 2002); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000). Thus, the MPEP is improper for the purpose for which the PTO seeks to use it.

Similarly, since promulgating the Final Rules, the PTO has published over two hundred pages of guidance documents, a portion of which the PTO now purports to rely upon in litigation to cure the vague preexamination search requirement of the ESD. (Manbeck Decl. ¶ 51.) Like the MPEP, however, the PTO may not rely on these guidance documents to cure the vagueness problem because they were not issued pursuant to notice and comment rulemaking. (*Id.*) As a result, these guidance documents should be set aside as violating the APA. *See Appalachian Power*, 208 F.3d at 1028 (setting aside guidance document as procedurally defective because it was an improper attempt at agency rulemaking).

Further demonstrating that the ESD is vague, the PTO cannot identify what steps would be sufficient to meet the preexamination search requirements. (Manbeck Decl. ¶ 49.) The ESD rule itself does not indicate what is sufficient (*see* Ex. 1 at 46,842-43 (Final Rule 265)), and the PTO failed to delineate the requirements in the Final Rules for a sufficient search. (*See* Manbeck Decl. ¶¶ 49-51.) Tellingly, in opposing GSK's request for preliminary relief, the PTO included a declaration purporting to describe the ESD's preexamination search, but even the PTO's own declarant failed to identify a search that would necessarily be sufficient. (*See* Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj., Ex. 4 (Decl. of Andrew I. Faile), at 9-10 ("[A] text search of appropriate databases ***may be*** all that is required."); *id.* at 10 ("If the supplied search adequately covers the relevant field of the invention, then it ***more than likely*** will be acceptable."); *id*. at 11 ("Final Rule 265 does not set forth . . . how a search ***must be carried out***. It may be performed . . . provided the areas where the most closely related art is likely to be found is included within the search."); *id.* at 11-12 ("[T]he ESD Guidelines teach that a text search of appropriate

databases ***may be*** all that is required.") (emphasis added).) Not once has the PTO articulated what would constitute a proper search. Thus, no reasonably prudent person could comply with the ESD requirements.[5]

F. The PTO Has No Authority To Implement The Final Rules Retroactively.

Regardless of whether the Final Rules are a valid exercise of the PTO's prospective rulemaking power, there can be no dispute that the PTO lacks authority to impose these rules retroactively. The Supreme Court has made clear that "[r]etroactivity is not favored in the law. . . . [A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules ***unless that power is conveyed by Congress in express terms***." *Bowen*, 488 U.S. at 208 (emphasis added) (citations omitted); *see also Landgraf v. USI Film Prods.*, 511 U.S. 244, 272-73 (1994); *Leland v. Fed. Ins. Admin.*, 934 F.2d 524, 527 (4th Cir. 1991). Congress has not expressly granted the PTO any retroactive rulemaking powers. *See* 35 U.S.C. § 2(b)(2). Despite this lack of authority, the PTO seeks to impose the Final Rules' restrictions on the backlog of more than 700,000 pending applications. (*See, e.g.*, Ex. A at 46,833.)

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[5] The PTO asserts that GSK's vagueness challenge fails because it lacks a protectable property interest. (Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 35-36.) The PTO's argument fails on two grounds. ***First***, GSK has brought a pre-enforcement challenge here, which does not require that patent applications be shown to be protectable property. The point of GSK's challenge here is that the vagueness of the Final Rules will frustrate GSK's ability to obtain patents that Congress has said GSK has a right to obtain if it meets certain statutory criteria. Indeed, as the Supreme Court explained in *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972), "[v]ague laws offend several important values," including that they "may trap the innocent by not providing fair warning." Those values are equally offended whether they are applied to frustrate the acquisition of rights or to deprive parties of already perfected rights. Here, Congress made clear in establishing an agency with limited powers over the patent grant that an inventor's right to a patent, and an unfettered path to obtain a patent, is protected. These strict rules and limits give rise to "a legitimate claim of entitlement" to a patent—granted by Congress—if the statutory path is followed. ***Second***, even if the PTO is correct that GSK must have a protectable property interest to prevail on its vagueness claim, its argument fails because GSK has such a protectable interest in its patent applications. *See* Section VII.G., *infra*.

A regulation is retroactive if "it would impair rights a party possessed when he acted . . . or impose new duties with respect to transactions already completed." *Landgraf*, 511 U.S. at 280. Here, the Final Rules are retroactive in both respects. ***First***, they "imposed new duties" that did not exist under the current system.[6] When GSK filed its currently pending patent applications, it possessed the right to file any number of continuing applications, RCEs, and claims as it deemed appropriate. (Manbeck Decl. ¶¶ 27-28, 32-34, 38, 45-46.) Under the Final Rules, however, GSK must file a petition and make a showing to exceed the PTO's limit on continuing applications and RCEs and also file an ESD to exceed the 5/25 claim limit. (*Id.* ¶¶ 40, 48.) Thus, the Final Rules impose "new duties" with respect to already-completed transactions—here, the already filed applications. *See Landgraf*, 511 U.S. at 280.

Second, the Final Rules are also retroactive because they "impair rights a party possessed when he acted." *See id.* When a party such as GSK conceives an invention, it has a choice to make in contemplating protection for that invention: protect the invention as a trade secret or seek patent protection by filing a patent application. (Manbeck Decl. ¶ 53.) A trade secret is a protectable property right. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984). When a patent application is filed, any trade secrets to the inventions disclosed in the patent application

[6] In opposing GSK's motion for preliminary relief, the PTO asserted that GSK's retroactivity claims fail because they neither impact vested "rights" nor impose new duties with respect to "transactions already completed." (Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 32-33 (citing *Landgraf*, 511 U.S. at 270 n.4).) *Landgraf*, however, is not as limited as the PTO contends. The Supreme Court expressly noted that it would ***not*** "restrict the presumption against statutory retroactivity to cases involving 'vested rights.'" *Landgraf*, 511 U.S. at 275 n.29. *Landgraf* makes clear that the retroactive inquiry does not hinge solely on property rights; an agency may also violate the retroactivity prohibition by "impos[ing] new duties" that did not exist in the prior regime. *Id.* at 280. The PTO does not deny that the Final Rules impose new duties—that is the essence of the Final Rules. Further, the PTO's assertion is flawed because GSK's argument does not turn on whether it has rights in pending applications, but whether the PTO has hindered its rights to follow the statutory path that Congress has delineated. Finally, even if GSK's retroactivity claims hinge on a protectable property interest, as set forth in Section VII.G., *infra*, the PTO is wrong that GSK lacks such an interest.

are relinquished in exchange for the opportunity to seek patent rights covering the full scope of the inventions. (Manbeck Decl. ¶ 53.) That opportunity includes the right to fully protect the inventions by filing any number of continuing applications, RCEs, and claims deemed appropriate by the applicant. (*Id*.) The Final Rules, however, retroactively alter that bargained-for exchange on which GSK and others relied upon when surrendering their trade secret rights for patent applications. (*Id.*) Under the Final Rules, GSK, and others like it, no longer possess the right to seek the appropriate spectrum of patent protection, nor can they reclaim their trade secrets disclosed in patent applications already filed and published. (*Id.*) Thus, the Final Rules "impair rights [GSK] possessed when [it] acted." *See Landgraf*, 511 U.S. at 280.

Moreover, in comments submitted during the rulemaking, the Patent Public Advisory Committee, an entity that functions as part of the PTO, urged the PTO not to impose the Final Rules' requirements retroactively. (*See* Ex. 25 at A01305 ("It would be manifestly unfair to applicants who have drafted their applications in reliance on present practice only to have the practice changed, to their detriment.").) That the PTO's own internal experts acknowledge and bemoan the retroactive effect of the Final Rules casts further doubt on the propriety of the PTO's litigation position, if indeed it does not foreclose it altogether. *Cf. Bowen*, 488 U.S. at 213 ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate.").

Finally, the PTO's argument that the Final Rules are not retroactive because they are procedural is incorrect. (*See* Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 33-34 (citing *Landgraf*).) First, as explained above, the Final Rules are substantive in nature. *See* Section VII.A, *supra*. Second, *Landgraf* does not support the PTO's position. *See Martin v. Hadix*, 527 U.S. 343, 359 (1999) (In *Landgraf*, the Court "took pains to dispel the 'suggest[ion] that

concerns about retroactivity have no application to procedural rules.'") (quoting *Landgraf*, 511 U.S. at 275 n. 29); *see also Brown v. Angelone*, 150 F.3d 370, 373 (4th Cir. 1998) (citing *Landgraf*).

In sum, changes to the rules for currently pending patent applications mid-stream—after such applications were drafted and filed with the existing set of rules in mind—are inherently retroactive and, therefore, unlawful under *Bowen* and its progeny.

G. The PTO's Failure To Adequately Consider The Final Rules' Taking Of Constitutionally Protected Property Rights In Patent Applications Was Arbitrary, Capricious, And Contrary To Law.

Patent applications, like patents themselves, are constitutionally protected private property. In *Ruckelshaus v. Monsanto Co.*, the Supreme Court held that trade secrets, like other intellectual property, are property protected by the Takings Clause, because "[t]rade secrets have many of the characteristics of more tangible forms of property." 467 U.S. at 1002-04. Like other protected property, trade secrets can be transferred and assigned, form the *res* of a trust, and pass to a trustee in bankruptcy. *Id.* The Supreme Court found these characteristics to be consistent with "a notion of 'property' that extends beyond land and tangible goods and includes the products of an individual's 'labour and invention.'" *Id.* at 1002-03.

Patent applications, which applicants obtain in exchange for disclosing their trade secrets, likewise contain key characteristics of protected property. (Manbeck Decl. ¶ 21.) Patent applications are transferable and assignable, *see* 35 U.S.C. § 261; patent applications can form the *res* of a trust, *see, e.g.*, *Conway v. White*, 292 F. 837, 843 (2d Cir. 1923); patent applications pass to the trustee in bankruptcy, *see, e.g.*, *Keen, Inc. v. Gecker*, 264 F. Supp. 2d 659, 662-63 (N.D. Ill. 2003); patent applications are taxable property, *Winchester v. Comm'r of Internal Revenue*, 27 B.T.A. 798, 801 (1933) ("It is now well settled that patent applications are property."); *see also Comm'r v. Stephens-Adamson Mfg. Co.*, 51 F.2d 681, 682 (7th Cir. 1931);

and patent applications provide provisional rights to collect damages for infringement, 35 U.S.C. § 154(d) (providing an applicant the right to obtain a reasonable royalty beginning on the date the patent application is published and ending on the date that the patent issues).[7] (*See also* Manbeck Decl. ¶ 21.)

The Final Rules threaten to destroy certain of GSK's patent applications and, hence, its patent rights in those inventions. The Final Rules' hard limitations on the number of continuing applications, RCEs, and claims that an applicant may seek effectively preclude GSK from adequately prosecuting patent applications that require more than two continuing applications, more than one RCE, or more than five independent or twenty-five total claims. In creating a regulatory scheme that strips GSK of the ability to fully and adequately patent its inventions—after GSK was induced to disclose its trade secrets in exchange for those patent applications—the Final Rules terminate substantial property rights of GSK and, therefore, operate or threaten to operate as a *per se* taking of GSK's property rights. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019-20 (1992).

The Final Rules also significantly threaten GSK's reliance interests and its valid expectations following the investment of huge amounts of capital. *See Penn Cent. Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978) (noting the three factors to consider in determining

[7] In opposing GSK's motion for preliminary relief, the PTO argued that patent applications do not give rise to property rights, citing four cases. (Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 33-34 (citing *Marsh v. Nichols, Shepard & Co.*, 128 U.S. 605, 612 (1888), *Mullins Mfg. Co. v. Booth*, 125 F.2d 660, 664 (6th Cir. 1942), *DeFerranti v. Lyndmark*, 30 App. D.C. 417, at *5 (1908), and *Brenner v. Ebbert*, 398 F.2d 762, 764-65 (D.C. Cir. 1968)).) These cases, however, are based on an outdated and incorrect notion that there are no property rights affiliated with patent applications. *See, e.g.*, 35 U.S.C. § 261 (originally enacted in 1952) and 154(d) (enacted in 1999). Further, each of the cases predates *Ruckelshaus*, the Supreme Court's most recent pronouncement that intellectual property is protected property under the Takings Clause. Under *Ruckelshaus*, patent applications are constitutionally protected property. As such, subsequent pronouncements have simply abrogated the PTO's outdated cases.

whether a regulatory taking occurs: character of the government action, economic impact of the regulation, and interference with reasonable investment-backed expectations). GSK annually invests billions of dollars in the research and development of life-saving pharmaceuticals. (Knowles Decl. ¶¶ 11-12.) To protect this investment, GSK relies heavily on patents and patent applications, including continuing patent applications. (*Id.* ¶¶ 13-19.) GSK has disclosed inventions (protectable trade secrets) to the public in its patent applications with the expectation that it will be afforded the opportunity to patent the fruits of its continued research and development efforts under the rules as they existed at the time of filing. (*Id.*)

The Final Rules substantially impact GSK's expectations by abridging GSK's ability to pursue its patent applications (and thereby protect its inventions). (*Id.* ¶¶ 41-48; Manbeck Decl. ¶¶ 29, 39, 47, 52.) If allowed to take effect, the Final Rules will effectively wipe out GSK's significant capital investments made in reliance on the existing patent application system. (Knowles Decl. ¶¶ 13-19, 41-48; *see also* Manbeck Decl. ¶¶ 29, 39, 47, 52, 53.) As a result, the Final Rules will alter GSK's preexisting property rights under the Patent Act, threatening an uncompensated and unconstitutional taking.

Agency action that fails to sufficiently and correctly address takings concerns expressed in public rulemaking comments is arbitrary and capricious and, thus, voidable. *See, e.g.*, *Nat'l Wildlife Fed'n v. ICC*, 850 F.2d 694, 705-08 (D.C. Cir. 1988) ("It is appropriate for the Commission to resolve this entirely separate 'takings' question in the first instance, free of the error that caused it prematurely to truncate its analysis in the proceeding below. . . . [W]e find the Commission's analysis of the takings issue raised by [the regulated party] insufficient to support its conclusion that the application of the Rules will never require compensation of reversionary owners."); *see also Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut.*

Auto Ins. Co., 463 U.S. 29, 43 (1983) (An agency rule is arbitrary and capricious "if the agency . . . [has] entirely failed to consider an important aspect of the problem.").

The PTO was well aware of the takings issues raised by the Final Rules. As the PTO acknowledged in the Final Rules, "[s]everal comments argued that . . . the new requirements would constitute a taking by the Federal Government." (Ex. 1 at 46,828.) Despite notice of this problem, the PTO failed to engage in a sufficient analysis, responding only that the 5/25 limit is not a taking:

> [T]he changes in this final rule do not preclude an applicant from filing an application or obtaining a patent containing any number of claims, but simply changes the procedures for applications containing more than five independent claims or more than twenty-five total claims. Therefore, there is no support for the proposition that the changes in this final rule amount to a "taking" by the government.

(Ex. 1 at 46,828.) This ignores the question of whether the new rules limiting continuing applications and RCEs constitute a taking and, hence, is self-evidently insufficient. Further, as addressed above, the PTO did more than alter the procedure for obtaining any number of claims. Rather, it imposed the hard 5/25 limit by requiring applicants to file the incomprehensible and vague ESD. The only other express reference in the Final Rules to takings issues is a one-sentence *ipse dixit* that "[t]his rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988)." (*Id.* at 46,834.) These conclusory responses by the PTO are woefully inadequate. *See Prof'l Pilots Fed'n v. FAA*, 118 F.3d 758, 771 (D.C. Cir. 1997) (stating that a court may not "sanction agency action when the agency merely offers conclusory and unsupported postulations in defense of its decisions").

Cursory analysis of important constitutional issues constitutes arbitrary and capricious rulemaking that is subject to vacatur under the APA.[8] *See* 5 U.S.C. § 706(2); *Nat'l Wildlife Fed'n v. ICC*, 850 F.2d at 708 (vacating an agency's regulation for insufficient and legally misinformed analysis of takings issues); *see also State Farm*, 463 U.S. at 43 (stating that an agency rule is arbitrary and capricious "if the agency . . . [has] entirely failed to consider an important aspect of the problem").

In sum, the PTO neglected its duty to fully consider the important issue of whether the Final Rules could result in the taking of private property without adequate compensation. Because the PTO did not act with the constitutionally compelled degree of caution and did not rationally address the legal challenges to its proposed rulemaking under the Takings Clause, this Court should vacate the retroactive provisions in the Final Rules under section 706(2) of the APA and remand for a new and legally accurate resolution of the takings question in the first instance. *Nat'l Wildlife Fed'n v. ICC*, 850 F.2d at 705; *see also Prill v. NLRB*, 755 F.2d 941,

[8] The arbitrary and capricious nature of the PTO's action is further exemplified by the fact that the agency has no authority to promulgate a regulation that could interfere with private property rights. It is well established that federal agencies may not exercise the federal government's eminent domain power unless Congress has expressly delegated that power. *See, e.g., United States v. N. Am. Transp. & Trading Co.*, 253 U.S. 330, 333 (1920) ("In order that the government shall be liable it must appear that the officer who has physically taken possession of the property was duly authorized so to do, either directly by Congress or by the official upon whom Congress conferred the power."); *Hooe v. United States*, 218 U.S. 322, 335-36 (1910) ("The taking of private property by an officer of the United States for public use, without being authorized, expressly or by necessary implication, to do so by some act of Congress, is not the act of the government."). *Compare Nat'l Wildlife Fed'n*, 850 F.2d at 694 (ICC, unlike the PTO here, engaged in a rulemaking determination only after recognizing that, under the statute, it had "neither an express delegation of condemnation power . . . nor [faced] terms implying that such a delegation was intended, nor any procedures governing the conduct of condemnation proceedings"). *See also Youngstown Sheet & Tube Co. v. Sawyer*, 103 F. Supp. 569, 575 (D.D.C.) (rejecting one of President Truman's justifications for seizing the Nation's steel mills because Congress had not delegated such eminent domain power to the President), *aff'd on other grounds*, 343 U.S. 579 (1952).

942 (D.C. Cir. 1985) ("[E]rroneous conception of the bounds of the law" by an agency requires vacatur and remand for the agency to act consistent with the true bounds of the law.).

H. In Addition To Its Substantive Defects, Final Rule 75 Is Procedurally Defective Because It Is Not A Logical Outgrowth Of The Proposed Rule.

The PTO so drastically changed the manner in which it would limit claims from its proposal in NPRM 2 to Final Rule 75 that the rule is defective for failure to comply with the APA's notice requirements. The APA's "notice requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Envt'l Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (quoting *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005)). Against this backdrop, a final rule must be vacated for improper notice unless it is a "logical outgrowth" of the proposed rule. *Id.*

"[A] final rule is a 'logical outgrowth' of a proposed rule only if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Int'l Union*,. 407 F.3d at 1259 (citation and internal quotation marks omitted); *see also Envt'l Integrity Project*, 425 F.3d at 996 ("The 'logical outgrowth' doctrine does not . . . apply where interested parties would have had to 'divine [the agency's] unspoken thoughts' . . . because the final rule was 'surprisingly distant' from the Agency's proposal." (citations omitted).).

Here, in NPRM 2, the PTO proposed requiring applicants to select "representative" claims for examination. NPRM 2 limited an applicant to ten representative claims before triggering the ESD filing requirement. (Ex. 6 at 63, 67 (Proposed Rule 75(b)(1).) The selected

representative claims could be a combination of independent and dependent claims. (*Id.* at 67 (Proposed Rule 75(b)(1).) The proposed rule, however, would have required that all independent claims be designated as representative, which would have effectively limited an applicant to ten independent claims. (*Id.*) Notably, the proposed rule did not require that any dependent claims be designated as "representative," and, thus, it did not restrict the total number of claims an applicant could seek. (*Id.* at 63 ("[T]he mere inclusion of a dependent claim in an application will not be considered a designation of the dependent claim for initial examination. . . . Thus, the applicant may designate a number of dependent claims up to ten minus the number of independent claims in the application to be given initial examination without filing an [ESD].").)

In response to the PTO's proposed rule, GSK and others submitted comments criticizing the proposed numerical thresholds and the ESD requirements. (Exs. 9, 12, 15 at A01503-06.) Despite this strident criticism, the Final Rules not only maintain arbitrary numerical thresholds but also impose more stringent restrictions. Final Rule 75 permits an applicant only five independent claims—a fifty percent reduction from the proposed rule. (Ex. 1 at 46,836-37.) Further, Final Rule 75 unexpectedly and inexplicably includes a limit on the total number of claims an applicant may seek before running into the onerous and vague ESD requirements. (*Id.*)

Interested parties, including GSK, could not have anticipated the PTO's harsher restrictions on the number of claims, particularly in view of the widespread opposition to the PTO's proposed rule. (*See* Manbeck Decl. ¶¶ 58-60.) In its proposed rule, the PTO indicated that only 1.2% of all applications would be affected by the representative claims proposal. (*Id.* ¶ 60; Ex. 6 at 66.) In sharp contrast, Final Rule 75's claim limitation would affect 23.7% of applications filed in fiscal year 2006. (Manbeck Decl. ¶ 60; Ex. 1 at 46,788.) The over 1800%

increase in affected applications is highly probative evidence of the impropriety of the PTO's change. (Manbeck Decl. ¶ 60.) In short, Final Rule 75 is not a logical outgrowth of the PTO's proposed rule.

Final rules that are not logical outgrowths of proposed agency rules violate the APA's notice and comment requirement for rulemaking. *See, e.g., Int'l Union,* 407 F.3d at 1259-61; *Chocolate Mfrs. Ass'n of the U.S. v. Block,* 755 F.2d 1098, 1106-07 (4th Cir. 1985); *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1275 (D.C. Cir. 1994); *Pub. Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7, 15 (D.D.C. 2006), *judgment amended*, 444 F. Supp. 2d 12 (D.D.C. 2006); *Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 15 (D.D.C. 2004), *modified by*, 2005 WL 1124589 (D.D.C. Apr. 6, 2005). The PTO could have cured this procedural violation by providing a notice and comment period for Final Rule 75 (although the rule would still be *ultra vires* because it is a substantive rule that is contrary to the Patent Act and case law). *See* 5 U.S.C. § 553(b). But, the PTO did not do so.

As a result, Final Rule 75's limits on the number of claims must be vacated because they were promulgated "without observance of procedure required by law." *See* 5 U.S.C. § 706(2)(D) (authorizing the setting aside of agency regulations issued in procedurally defective ways).

I. The Final Rules' Mechanical Limits On Continuing Applications, RCEs, And Claims Are Arbitrary And Capricious.

The Final Rules are arbitrary and capricious for two additional reasons. First, in promulgating the Final Rules, the PTO has mistaken the limits of its statutory authority, rendering the Final Rules *per se* arbitrary and capricious. *See Prill*, 755 F.2d at 942 (finding that an agency's action based on a misunderstanding of the law was arbitrary and capricious and must be vacated and remanded for the agency to act consistent with the true bounds of the law). *Prill* is a modern expression of the Supreme Court's landmark decision in administrative law, *SEC v.*

Chenery Corp.: "[I]f [agency] action is based upon a determination of law as to which the reviewing authority of the courts does come into play, an order may not stand if the agency has misconceived the law. . . . [T]he orderly functioning of the process of review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained." 318 U.S. 80, 94 (1943). In other words, an agency's view of the scope of its own authority is the foundation on which any rulemaking is built; if the agency misconceives that foundation, everything built upon it is arbitrary and capricious and must similarly be vacated. *See id.* Here, because the PTO misperceived the limits of its statutory authority, the Final Rules are arbitrary and capricious.

In addition, the PTO's justification for its actions—administrative efficiency—also renders the Final Rules arbitrary and capricious, as the PTO has not adequately explained this justification. *See State Farm*, 463 U.S. at 48-49 (instructing that agency decisions that are not adequately explained, fail to consider important alternatives, and not supported by the data an agency cites are arbitrary and capricious and should be set aside under 5 U.S.C. § 706(2)); *NRDC v. Thomas*, 838 F.2d 1224, 1253 (D.C. Cir. 1988) ("EPA's rejection of both these alternatives is unexplained, leaving the claim of undue enforcement difficulty inadequately supported.").

In opposing GSK's request for preliminary relief, the PTO relied on a single document to show that the "Final Rules will have an appreciable impact on the backlog." (*See* Defs.' Opp. Pls.' Mot. TRO and Prelim. Inj. 32 (citing Ex. 26 hereto at A05641-721).) That document, however, relies on unexplained assumptions and fails to support the PTO's assertions. (Manbeck Decl. ¶¶ 54-56.) Page A05645, on which the PTO relies, assumes that "Calims [sic],

Continuations & IDS (Examiner Bonus Structure)" will have a one percent reduction in fiscal year 2008 and then a two percent reduction in each of fiscal years 2009 through 2013.[9] (Ex. 26.)

As an initial matter, the alleged efficiency gains do not account whatsoever for the new limit on RCEs. Regarding claims and continuation applications, there is no indication where the supposed efficiency gains come from or how they are broken down between the three purported sources of such gains. (Manbeck Decl. ¶ 55.) Regarding IDS's, the IDS rule is a separate proposed rule that has not yet been promulgated in final form.[10] (*Id.* ¶ 57.) And, regarding bonuses, nothing explains what the bare reference to "Examiner Bonus Structure" could mean. (*Id.*) The Final Rules themselves contain only two references to bonuses and their potential to help reduce the PTO's backlog: (1) an indication that the PTO was looking into future reforms in bonus structures;[11] and (2) a response to a comment, one page later, suggesting that better bonuses were not needed.[12] (*Id.*) These two references to bonuses are internally inconsistent, which further demonstrates the arbitrary and capricious nature of the PTO's actions. *See, e.g.*, *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 850-55 (D.C. Cir. 1987) (finding that

[9] It is unclear what many of the abbreviated row and column headings mean on the output sheets on which the PTO relies, and summary judgment briefing is too late for the PTO to attempt to explain the spreadsheet outputs for the first time. *See Am. Mining Congress v. EPA*, 907 F.2d 1179, 1188 (D.C. Cir. 1990); *see also State Farm*, 463 U.S. at 50.

[10] *See* Changes To Information Disclosure Statement Requirements and Other Related Matters, 71 Fed. Reg. 38,808 (July 10, 2006) (proposed rule).

[11] *See* Ex. 1 at 46,817 ("The Office recognizes that hiring alone will not reduce the backlog of pending applications in the near future. As a result, the Office is actively seeking ways for retaining more employees, such as retention bonuses.")

[12] *See* Ex. 1 at 46,818 ("A number of comments suggested that the Office could retain more examiners by increasing compensation and offering better working conditions . . . . One comment stated that a bonus system should be established . . . . [The PTO's] Response [is]: . . . . The Office already provides a robust bonus system for examiners that enables one to earn up to ten percent of one's salary per year in bonus compensation.")

Interstate Commerce Commission's explanation of geographic competition was internally inconsistent and thus arbitrary and capricious).

Moreover, all that the record contains is the output of whatever spreadsheet the PTO created, with no explanation of the PTO's analysis. (Manbeck Decl. ¶ 55.) *See also State Farm*, 463 U.S. at 43 (agency action taken without a "rational connection between the facts found and the choice made" is arbitrary and capricious); *Owner-Operator Indep. Driver Ass'n, Inc. v. Fed. Motor Carrier Safety Adm'n*, 494 F.3d 188, 202 (D.C. Cir. 2007) ("We have no difficulty in concluding that the agency's failure to disclose the methodology of the operator–fatigue model in time for comment was prejudicial.").

In addition to not disclosing its methodology, the one referenced document contains errors and/or unexplained internal inconsistencies. *See NSK Ltd. v. United States*, 390 F.3d 1352, 1357-58 (Fed. Cir. 2004) (vacating agency decision where agency interpreted statutory provisions in an internally inconsistent fashion and failed to reasonably explain the inconsistency). For example, A05645 identifies "Efficiency Gains" that total 6.5% in fiscal year 2008 and 7.5% in 2009-2013, yet the "Model assumptions" identify efficiency gains of only 2.0% and 5.5%, respectively. (*Compare* Ex. 26 at A05645 *with id.* at A05646.) Similarly, the summary and the assumptions of the "Chap I and Chap II" PCT reductions do not match. (*Compare id.* at A05645 *with id.* at A05646.)

Furthermore, the data assumes hard limits on the number of continuing applications and claims that the PTO will allow, but does not account for the additional burdens imposed on the PTO when applicants submit newly required supplemental filings. (Manbeck Decl. ¶ 56.) For example, in determining its assumed efficiency gains, the PTO does not appear to have taken into account that some applicants will file ESDs to exceed the 5/25 limit. (*Id.*) In that event, any

efficiency gains will be offset by the additional administrative burdens of analyzing the filed ESDs. (*Id.*) A more likely explanation for this omission—as the PTO has conceded to the public—is that it expects most applicants to abide by the 5/25 limit to avoid triggering the onerous ESD requirement and the attendant risk that filing an ESD will result in allegations of inequitable conduct in subsequent litigation. (*Id.*) Be that as it may, the PTO cannot have it both ways—either the ESD requirement is a viable alternative path to obtaining more claims or it is not. If it is not, the claims limitation is unavoidably *ultra vires*. If the ESD is a viable route to adding claims, then the evidence that the PTO itself believed that to be true is conspicuously lacking from the record. The modeling that the PTO offered in support of the Final Rules efficiency gains assumes linear workload reductions based on claims limitations. (*Id.*) There is no record of dynamic modeling that accounts for the multiple variables that impact efficiency. (*Id.*)

In short, the PTO's so-called models and assumptions fail to provide a reasoned explanation for the Final Rules' mechanical restrictions on continuing applications, RCEs, and the number of claims an applicant may submit. *See Appalachian Power Co. v. Train*, 545 F.2d 1351, 1363 (4th Cir. 1976). Thus, the Final Rules are arbitrary and capricious.

VIII. CONCLUSION

For the foregoing reasons, GSK respectfully submits that it is entitled to judgment as a matter of law on each of the counts in its amended complaint. Accordingly, GSK respectfully requests that the Court enter judgment that the Final Rules are invalid, vacate the Final Rules, and grant a permanent injunction against their enforcement.

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Respectfully submitted,

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Notice through the CM/ECF system also will be sent to the proposed *amicus curiae* parties whose motions for leave to appear are still pending.

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