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

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED, d/b/a GLAXOSMITHKLINE,	:	
Plaintiffs,	:	
v.	:	**Civil Action No. 1:07cv1008**
JON W. DUDAS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and	:	
UNITED STATES PATENT AND TRADEMARK OFFICE,	:	
Defendants.	:	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff GSK respectfully requests that the Court grant a temporary restraining order and a preliminary injunction enjoining the Patent and Trademark Office ("PTO") from implementing the PTO's "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications," 72 Fed. Reg. 46716 (Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1) ("the Final Rules"). Ex. A.

Preliminary relief will maintain the status quo until the Court has the opportunity to render a final decision on the merits of the Final Rules. GSK readily meets the familiar standard for granting preliminary injunctive relief. The Final Rules dramatically upset longstanding congressional patent protections and do so to the great prejudice of a company, GSK, and an industry, pharmaceuticals, where patent protection is indispensable.

First, GSK is likely to succeed on the merits because the Final Rules' restrictions are *ultra vires*—the rules are clearly substantive in nature, but Congress has not given the PTO any substantive rulemaking authority. Moreover, the rules apply retroactively. Congress rarely grants agencies retroactive rulemaking authority, and must do so explicitly. There is simply no evidence in the Patent Act that Congress granted the PTO retroactive rulemaking power. Further, by restricting the number of continuing applications, the number of requests for continued examination ("RCEs"), and the number of claims an applicant may file, the Final Rules are contrary to the express language of the governing statutes. In addition, certain of the Final Rules are incomprehensibly vague and fail to provide GSK with sufficient notice as to how to comply, frustrating GSK's ability to rationally organize its business activities.

Second, GSK will be irreparably harmed if the Final Rules go into effect and are later invalidated. GSK will lose patentable subject matter and inventions in pending patent applications for which it has devoted valuable employee time and financial investment because

GSK will not be able to file additional continuing applications after November 1, 2007 that claim these inventions. Since GSK will not know whether the Final Rules will be ultimately stricken, and whether it can ever rightfully recover lost patentable inventions, GSK may be forced to make strategic decisions not to proceed with the development of some inventive drugs because of the very real risk that patent protection will be unavailable.

Moreover, the PTO's insupportable assertion of retroactive rulemaking power will harm GSK's already-filed patent applications. The Final Rules preclude GSK from filing more than one parent and two continuing applications without filing a petition and showing that the reason(s) for any additional continuing application "could not have been" presented earlier.[1] Presently, GSK has approximately one hundred or more pending application families with two or more continuing applications and/or one RCE, which will be governed by the new "could not have been submitted" earlier standard.[2] As a result of this new and retroactive standard, GSK will be deprived of the ability to fully patent additional aspects of its disclosed inventions. GSK also has several pending patent applications that will trigger an immediate requirement to file an examination support document ("ESD") on November 1, 2007. GSK will then be forced to comply with the ESD's incomprehensibly vague preexamination search requirement.

Third, the balance of hardships tips decidedly in GSK's favor. The potential harm to GSK is unquestionable, significant, and irreversible. Conversely, if the PTO were prevented

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[1] Although the PTO has issued guidance that purports to provide "one more" continuation as of right before it imposes this new standard, that guidance is contrary to the Final Rules, and does not address the situation where GSK needs more continuations than the "one more." Further, on October 10, 2007, the PTO issued an *ad hoc* "clarification" that created exceptions to the "one more" rule for applications claiming priority to a divisional application. But those exceptions do not apply to GSK's example, discussed herein, because it does not involve a divisional.

[2] One example of an affected application family is described in paragraphs 23-39 of the Declaration of Sherry M. Knowles submitted in support of this motion.

from implementing the Final Rules until an ultimate decision on the merits, the PTO would merely be operating under the status quo that has served patent applicants, the American medical system, and the public well for decades. Moreover, delaying implementation of the Final Rules will impact the PTO only minimally, if at all, because the PTO has conceded that the Final Rules, which it asserts are designed to reduce application backlogs, represent a paltry, token effort in that direction. Indeed, the PTO has admitted that the rules concerning continuing applications will affect less than 2.7 percent of all pending patent applications.

Fourth, the public interest favors enjoining the PTO from implementing the Final Rules. The highest public interest is human health. The public needs GSK, and other innovator companies like it, to invest substantial sums of money to develop new life-saving drugs. It is not in the public interest to remove the incentives for GSK to pioneer new drugs, or to cause GSK to drop a research program on a life-saving drug because of a loss of patent rights.

II. STATEMENT OF FACTS

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

GSK is the second largest pharmaceutical company in the world. Ex. B, Decl. of Sherry M. Knowles in Supp. of Pls.' Mot. for a TRO and Prelim. Inj. (hereinafter, "Knowles Decl.") ¶ 6. 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. This drug research necessarily requires a large, up-front, totally at-risk investment. *Id.* ¶ 9. Indeed, in 2006, GSK invested $6.4 billion, or approximately $18 million per day, on drug research and development. *Id.* ¶ 12. The 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 or more dollars in

investment. Verified Am. Compl., Dkt. No. 5, ¶¶ 52, 54. The research and development of drugs is fraught with many hurdles, ultimately leading to thousands of rejected drugs for each successful drug brought to market. *Id.* ¶ 31. Further, the FDA's strict regulations explain, in part, why the financial cost to GSK to discover and develop a new drug can exceed $1 billion. *Id.* ¶ 54; Knowles Decl. ¶¶ 8, 11.

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

Patents play an important role in encouraging GSK to invest in the discovery and development of new drugs. GSK relies on patent protection for drug products successfully brought to market to finance its up-front investments in research and development. Knowles Decl. ¶ 13. This investment includes losses incurred in failed drug development efforts. *Id.* ¶ 10. The current laws provide robust patent protection, important to GSK's business.

Under the current patent system and its well-established incentives, GSK has brought to market many innovative and beneficial drugs. For example, in recent years, GSK has brought to the American public Zofran (for alleviating nausea and vomiting associated with chemotherapy and radiotherapy for cancer); Valtrex (for managing herpes simplex and herpes zoster); Advair (for asthma and other airway obstruction disorders); Imitrex (for migraine headache); Avodart (for enlarged prostate); Epivir, Combivir, and Trizivir (for HIV); and Coreg (for treating mild-to-severe chronic heart failure), to name only a few. *Id.* ¶ 16. After more than ten years of research and development, GSK also recently launched Tykerb in the United States for the treatment of advanced stage and metastatic breast cancer. *Id.* The current patent system is important to GSK for recovering the significant costs of development and regulatory approval associated with these and other drugs. Knowles Decl. ¶ 17.

Without strong patent protection, a new drug would be copied and sold by others who did not incur the billions of dollars in research investments borne by an innovator company like GSK. *Id.* ¶ 14. In other words, without patent protection or with inadequate protection, GSK would not undertake the huge investment 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. Continuing Applications And Their Importance To GSK.

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 a first patent application containing a broad disclosure with the understanding that it will prosecute narrower and/or additional patent claims in continuing applications, based on further extensive research. *Id.* For example, if the selected drug fails in expensive clinical trials, GSK can select an alternative and file continuing patent applications to protect the new lead candidate.

In a typical GSK patent application on a new class of chemical compounds, the disclosure will include a number of inventions. One example of such a GSK application pertains to compounds for the treatment of the inflammatory component of certain diseases, including asthma and atherosclerosis. *Id.* ¶¶ 23-39. 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* Knowles Decl. ¶ 24, Ex. 1. 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).

Knowles Decl. ¶¶ 24, 34, Ex 1. 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 filed ("the priority date"). *See* Ex. E, Decl. of Harry F. Manbeck, Jr. (hereinafter "Manbeck Decl.") ¶¶ 16-18. This priority date serves as the "stake in the ground" for the invention. The date serves to mark what information can be used to assess the patentability of the invention. *Id.* ¶¶ 14-15. Publications and other public information dated before the priority date can be used to support arguments against the patentability of the invention, while those dated after the priority date cannot. *See id.* Thus, it is critical that all continuing patent applications that present additional portions of the inventions get the benefit of this "stake in the ground." *Id.* ¶¶ 14-15, 19. If not, publications and

public information between the priority date and the date of the later-filed application can be used against patentability, including the publication of the initial application itself. *Id.* ¶ 19.

In the case of the '551 patent, a comparison of the list above to the claims at the back of the patent (at Cols. 68-84) shows that not all of the available subject matter has yet been claimed. The remaining inventions would normally be presented in continuing applications. Knowles Decl. ¶¶ 35-39. But under the Final Rules, GSK would be prevented from prosecuting additional subject matter in that patent family. *Id.* ¶¶ 41-43. The right to patent those inventions will be lost.

D. The Patent Act Does Not Limit The Number Of Continuing Applications.

As early as 1863, the Patent Act was understood to allow an applicant to file continuation patent applications. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863). In the ensuing years, the case law further clarified that the patent laws did not limit the number of continuing applications an applicant could file. *See* Verified Am. Compl. ¶ 44; Manbeck Decl. ¶¶ 25-28.

In 1952, Congress codified then-existing law when it enacted 35 U.S.C. § 120. *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. *See* Act of July 19, 1952, Pub. L. No. 593, ch. 950, 66 Stat. 800, *reprinted in* 1952 U.S.C.C.A.N. 761. 30.

Congress has amended Section 120 only minimally since 1952. For example, in 1999, Congress amended Section 120 to provide the Director with limited discretion in determining when to enter a late amendment of the application to comply with formal defects. *See* Pub. L. No. 106-113, § 4503(b)(1), 113 Stat. 1501, 1501A-563 to 1501A-564 (1999). Congress has never given the PTO or the Director any other discretionary authority insofar as continuation applications are concerned. *See* Manbeck Decl. ¶ 31.

Since Congress enacted Section 120, the courts have consistently stated that the PTO cannot limit the number of continuation applications an applicant could file. *See In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (stating that the PTO had "no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications, provided applicant meets all the other conditions of the [§120] statute."). Subsequently, the PTO itself recognized that, under *Henriksen*, it lacked the authority to limit the number of continuation applications that an applicant was permitted to file. *See Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975) (stating that *Henriksen* "established that the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved"). Courts have continued to construe Section 120 broadly. Verified Am. Compl. ¶ 50.

E. The Patent Act Requires The PTO To Grant A Request For Continued Examination.

To promote efficiency in the examination process and to avoid needless appeals of claim rejections by examiners at the PTO, Congress amended 35 U.S.C. § 132(b) to allow for RCEs of an application. Section 132(b) provides that "[t]he Director ***shall*** prescribe regulations to provide for the continued examination of applications for patent ***at the request of the applicant***." (Emphasis added.) Congress has not authorized the PTO to limit the number of RCEs that an applicant may file, as Section 132(a) states that the PTO "***shall***" continue examination upon request. 35 U.S.C. § 132(a); Manbeck Decl. ¶¶ 34-35.

F. The Patent Act Does Not Authorize The PTO To Impose Barriers That Restrict The Number Of Claims An Application May Contain.

An inventor has a statutory right to a patent unless the invention that is the subject of the application for the patent is not new or 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. 35 U.S.C. §§ 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." These statutes are the *only* statutory restrictions on claim presentation. Manbeck Decl. ¶¶ 32-33.

G. The PTO's Proposed And Final Rules.

In January 2006, the PTO proposed several changes to its rules, including to its rules regarding continuing applications, RCEs, and claims. In response to request for comments on the PTO's proposed rules, GSK, professional organizations, and business entities critiqued both the substance of the proposed rules and offered constructive alternatives. *See, e.g.*, Ex. C. 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. *Id*. GSK and others also commented that the proposed rules were beyond the PTO's statutory authority. *Id*. Nonetheless, the PTO marched forward.

1. The Final Rules Will Restrict Patent Applicants To Only Two Continuing Applications Without Filing A Petition.

The Final Rules will restrict patent applicants to no more than two nonprovisional continuing applications before requiring a petition showing that the amendment, arguments, or evidence ***could not have been*** submitted during the prosecution of the prior-filed application. *See* Ex. A at 46839. For a particular continuing application, if GSK cannot satisfy the "could not have been submitted" showing, it will lose the benefit of priority it was otherwise entitled to under 35 U.S.C. §§ 120, 121, or 365(c).

The "could not have been submitted" standard is tantamount to a "physical impossibility" standard that contradicts the current law and precludes an applicant in almost all circumstances from being granted a petition for a third continuing application. Indeed, in responding to

comments, the PTO confirmed that it considers almost all circumstances insufficient under that standard. *See* Ex. A at 46772-77 (responses to Comments 80 through 100); *see also* Verified Am. Compl. ¶ 40. Further, the "could not have been submitted" standard places GSK in the position of either averring that it physically could not have presented an amendment before (and risking a violation of its ethical obligations to the PTO under § 10.85) or not filing a petition and losing its current right to prosecute additional patent claims on its inventions. *See* Manbeck Decl. ¶¶ 45-47. Exacerbating the negative impact of these new continuing application rules is the fact that the PTO will apply the new restrictions retroactively.

2. The Final Rules Significantly Change RCE Practice.

The Final Rules permit an applicant only a single RCE in a patent family before requiring an applicant to file a petition and "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. A at 46841 (emphasis added). The Final Rules apply the new limitation on RCEs 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. *Id.* at 46717.

3. The Final Rules Restrict The Number Of Claims An Applicant May Prosecute.

The Final Rules also restrict an applicant to five independent claims and a total number of twenty-five claims before requiring an applicant to file an ESD. *See* Ex. A at 46836-37 (§ 1.75(b) as adopted). The ESD imposes incomprehensible 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.[3] *Id.* at 46842 (§ 1.265(b) as adopted). The Final Rules apply the ESD requirements retroactively, applying them to any pending application that has not yet received a first Office Action from the PTO on the merits. *Id.* at 46716.

H. The Current State Of GSK's Patent Applications.

Presently, GSK has approximately one hundred or more pending applications in which two or more continuing applications have been filed, and approximately thirty or more pending applications in which two or more continuing applications and a RCE have been filed. *See* Knowles Decl. ¶¶ 20-21. Further, GSK has identified several pending applications that have not yet received an Office Action on the merits and that contain a sufficient number of claims to trigger an ESD. *Id.* ¶ 22. Even though these applications were submitted and prosecuted under the current, well-established PTO rules, the Final Rules apply retroactively and, therefore, after the Final Rules become effective on November 1st, the requirement to file an ESD will be triggered for each of these applications causing GSK irreparable harm. *Id.* ¶ 45.

An example of a GSK patent application family affected by the Final Rules is U.S. Patent Application Serial No. 11/871,039. *Id.* ¶¶ 23-39. That application was filed on October 11, 2007, and is the third continuation application in the '551 family. *Id.* ¶ 27, Ex. 2. Under the current system, GSK could file additional continuing applications to add new claims directed towards disclosed, but not previously claimed, subject matter. *Id.* ¶ 40. But now, the Final

[3] The Patent Reform Act of 2007 would, if passed by Congress, amend 35 U.S.C. to add a new § 123 entitled "Additional Information" that grants the PTO the authority to request patent applicants to carry out a search for relevant art (but does not provide the specifics of how it is to be done). Congress has not yet passed this Act, but the provision confirms that the PTO currently lacks the right to delegate this responsibility to applicants. Further, this provision would not cure the vagueness of 37 C.F.R. § 1.265 described herein.

Rules, and GSK's ethical obligations to the PTO, will impose risks on GSK, deterring it from filing additional continuing applications authorized by Congress, and thus irreparably injuring GSK. *Id.* ¶¶ 41-44, Ex. 3.

III. ARGUMENT

A. Legal Standard For A Temporary Restraining Order And A Preliminary Injunction.

To be entitled to a preliminary injunction, GSK must show that: (1) it is likely to succeed on the merits; (2) it will be irreparably harmed; (3) the balance of the hardships tips in its favor; and (4) the public interest is in its favor. *See Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007);[4] *cf. Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189, 196 (4th Cir. 1977). The standard for granting a temporary restraining order is the same as that for granting a preliminary injunction. *See Moore v. Kempthorne*, 464 F. Supp. 2d 519, 525 (E.D. Va. 2006) (citations omitted).

Federal courts preliminarily enjoin federal regulations that are likely to be ruled unlawful or where equity otherwise dictates, and, indeed, must do so where the balance of equitable factors favors the plaintiffs assailing such governmental regulation.[5]

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[4] As this case concerns substantive patent law, the law of the Federal Circuit applies to the issuance of a preliminary injunction. *See Texas Instruments, Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1328 (Fed. Cir. 2000).

[5] *See Select Milk Producers, Inc. v. Johanns*, 400 F.3d 939, 941 (D.C. Cir. 2005) ("On January 31, 2001, the District Court granted Milk Producers' motion for a preliminary injunction enjoining the Secretary from imposing [by regulation] a separate price for Class III butterfat. The Government did not appeal the preliminary injunction or otherwise seek to defend its position."); *National Ass'n of Farmworker Orgs. v. Marshall*, 628 F.2d 604, 616 (D.C. Cir. 1980) ("It may well be that a preliminary injunction [against Department of Labor approval regulations for certain pesticide uses] was warranted even if the district court had correctly concluded that plaintiffs would not be likely to prevail on the merits. Even if that were the case, plaintiffs needed only to present a 'serious legal question' for preliminary relief to be granted under the other circumstances of their case."); *accord Hazardous Waste Treatment Council v. South Carolina*, 945 F.2d 781, 787 (4th Cir. 1991).

B. GSK's Claims Are Justiciable.

To ward off a similar challenge in *Tafas*, the government moved to dismiss most of Mr. Tafas' claims as non-justiciable, arguing that Mr. Tafas lacks standing or his claims are not ripe. *See Tafas v. Dudas*, 1:07-cv-00846-JCC-TRJ, Dkt. Nos. 17 and 18 (E.D. Va. filed Aug. 22, 2007). Whatever the validity of the PTO's defenses to that complaint, it is clear that GSK's Verified Amended Complaint meets the standing and ripeness tests.

"As the Supreme Court explained in [*Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)], the burden of production a plaintiff must bear in order to show it has standing to invoke the jurisdiction of the district court varies with the procedural context of the case. At the pleading stage, 'general factual allegations of injury resulting from the defendant's conduct may suffice,' and the court 'presum[es] that general allegations embrace the specific facts that are necessary to support the claim.'" *Sierra Club v. EPA*, 292 F.3d 895, 898-99 (D.C. Cir. 2002) (quoting *Lujan*, 504 U.S. at 561). Logic demands that ripeness be tested by a similar rule. Nothing in the antitrust case of *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007), alters the Supreme Court's existing rules on the proper procedural development of standing allegations, especially as advanced against government regulatory action. *See Rodriguez de Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989) (lower courts lack the power to declare Supreme Court decisions overruled by implication).

It is clear that GSK has alleged sufficient facts in its Verified Amended Complaint (as supplemented herein) to support standing. *See* Verified Am. Compl. ¶¶ 34-43, 52-58, 92-94, 100-53; Knowles Decl. ¶¶ 5-48. GSK maintains it is a regulated party that frequently files patent applications and the Final Rules will directly injure GSK; that the Final Rules cause injury by changing the regulatory status quo; and that an injunction against or vacatur of the Final Rules will redress GSK's injury. These are the entirety of the Article III standing requirements. *See*

Marshall v. Meadows, 105 F.3d 904, 906 (4th Cir. 1997) ("There are three basic components of standing: injury, causation, and redressability."). Indeed, the Supreme Court has indicated that in situations like this, the standing of a party like GSK is self-evident. *See Lujan*, 504 U.S. at 561-62 ("[If a plaintiff] himself [is] an object of the action (or forgone action) at issue . . . there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.").

As to ripeness, GSK also readily meets the two-part test established in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). GSK does not expect the government to seriously contest that the challenges presented here are purely legal questions fit for review. *See Fort Sumter Tours, Inc. v. Andrus*, 564 F.2d 1119, 1123 (4th Cir. 1977) (applying *Abbott Laboratories* and noting that legal issues are "traditionally within the competence of the judicial branch."). That leaves only hardship. The Verified Amended Complaint adequately alleges the hardship the Final Rules pose to GSK's patent decision-making, compliance costs, and need to avoid adverse enforcement consequences. *See* Verified Am. Compl. ¶¶ 92-94.

As the D.C. Circuit has recognized, and Justice Breyer observed in his widely used administrative law casebook, agency rulemakings are uniquely and typically appropriate for preenforcement review under the *Abbott Laboratories* test: "In the three decades since *Abbott Laboratories*, preenforcement review of agency rules and regulations has become the norm, not the exception, [Stephen G. Breyer & Richard B. Stewart, *Administrative Law and Regulatory Policy* 1137 (2d ed. 1985)] . . . ." *Clean Air Implementation Project v. EPA*, 150 F.3d 1200, 1204 (D.C. Cir. 1998). The Final Rules are *ultra vires* acts that usurp an interpretive power exclusively conferred by Congress on the courts. *See infra* § III.C.1; Verified Am. Compl. ¶¶ 100-07. Hence, prudential ripeness concerns here cry out for preenforcement review, so that the

pivotal question of the PTO's authority to issue rules of this sort can be settled now, rather than requiring parties like GSK to establish the illegality of the Final Rules on a piecemeal basis in individual PTO enforcement actions—thereby proportionally multiplying GSK's hardship.

C. GSK Is Likely To Succeed On The Merits.

1. The Final Rules Are All *Ultra Vires* Because The PTO Lacks The Authority To Issue Substantive Rules.

Congress has not vested the PTO with substantive rulemaking authority. Congress granted the PTO limited rulemaking authority in 35 U.S.C. § 2(b)(2). *See* Manbeck Decl. ¶¶ 6-7. Section 2(b)(2) authorizes the PTO to "establish regulations, not inconsistent with law" for a list of enumerated purposes. The relevant provisions of § 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).

Section 2(b)(2)'s structure as an enumeration of rulemaking powers covering specific subjects restricts the PTO to regulating those subjects, and those subjects alone. Moreover, the Federal Circuit has held that the PTO and Director lack "any general substantive rulemaking power." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996). Instead, even at their zenith, the rulemaking powers of the PTO and Director are directed only to governing "the conduct of proceedings ***in*** the [PTO]." *Id.* (emphasis added). Nothing in the legislative history of § 2(b)(2) alters the legal conclusion reached in *Merck*. The Federal Circuit reaffirmed its continued agreement with the *Merck* holding as recently as 2003 in *Eli Lilly & Co. v. Board of Regents of University of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003).

Deference to agencies under the familiar test of *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984), is unavailable where Congress has conferred the power to construe the relevant provisions of one of its enactments exclusively upon the courts and not upon an agency. *See*

Adams Fruit Co. v. Barrett, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."). Here, the PTO is not owed any *Chevron* deference because Congress did not grant the PTO authority to construe the provisions of the Patent Act (except where specifically enumerated). On the contrary, in the Federal Courts Improvement Act of 1982, Congress centralized review of cases involving constructions of the patent laws in the Federal Circuit. Verified Am. Compl. ¶ 103.

As written by Congress, the patent laws do not limit the number of continuing applications, RCEs, or claims that may be filed. They do not grant the Director the authority or discretion to limit those filings; nor do they grant the Director authority to impose retroactive limitations. Rather, the patent laws provide the Director narrowly defined powers so that the Director can facilitate the allowance of applications that satisfy the conditions for patentability. Contrary to these clear limits long observed by the PTO and its predecessor agencies, 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. The PTO lacks any such power.

The PTO's lack of substantive rulemaking authority is further evidenced by the fact that since 2005, Congress has considered giving the PTO such substantive rulemaking authority. Manbeck Decl. ¶ 11. Indeed, last month, the House of Representatives passed the Patent Reform Act of 2007, H.R. 1908, which proposed giving the PTO substantive authority to issue rules that interpret 35 U.S.C. §§ 120, 121 and 365(c). *See* H.R. 1908, 110th Cong., § 14(a) (2007). This proposed statutory language is a remarkable expansion of the law that, to date, the Senate has not endorsed. Further, even in H.R. 1908, Congress would retain oversight over the PTO's rulemaking with a review period and veto right. *Id.* § 14(c). Thus, under H.R. 1908, the House

still has not entrusted the PTO with plenary authority under those sections. In short, regardless of whether the bill passes, the PTO did not possess substantive rulemaking authority at the time it issued the Final Rules. And even if Congress grants the PTO the proposed substantive rulemaking authority at some point in time, that authority would not support the sweeping changes set forth in the Final Rules; nor would it overcome the severe defects in the Final Rules explained herein and in GSK's Verified Amended Complaint, ¶¶ 100-107, 119-153.

2. The PTO Lacks The Authority To Impose The Final Rules' New Restrictions Concerning Continuing Applications.

a. The Restrictions On Continuing Applications Exceed The Plain Language Of Section 120.

The Final Rules' proscriptions on continuing applications exceed the plain language of § 120 of the patent laws. Section 120 does not limit the number of continuation applications an applicant may file:

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

But the PTO, in amending Rule 1.78 in the Final Rules, restricts applicants, including GSK, to only two continuing applications (without the need for filing a petition and making a specified showing). That regulatory amendment violates the express language of Section 120, which states that a continuation application "shall" have 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.

Section 120 provides the Director with discretion as to only one issue—to determine under what circumstances the PTO will accept a late amendment to the specification to include a required reference to earlier-filed claims. Section 120 does not provide the Director or the PTO

with any other discretion. As a result, in exercising discretion to determine when an applicant may file a continuation, the PTO has overstepped its congressionally authorized powers. The Fourth Circuit explained the proper approach to *Chevron* questions of this nature—*i.e.*, when an agency is empowered with some administrative authority, but exceeds the bounds of its delegation:

> [W]hen we determine that no delegation can be implied, as when the task of the agency is merely to perform a ministerial calculation or to issue a document whose contents are dictated in detail by the statute, we do not afford the agency the type of deference we otherwise would afford if the agency acted by delegation in Congress' stead. For those kinds of tasks, Congress has already spoken and its words are cast. The opinions of agencies pursuant to such provisions do not carry the imprimatur of delegation. Even though the task may require the agency to make interpretive decisions, produce a binding rule, or issue a mandate in its field of expertise, we need not yield because there is no predicate delegation as required by [*United States v.*]*Mead*[, 533 U.S. 218, 231-32 (2001) (applying the delegation-as-precondition-*Chevron*-deference rule of *Adams Fruit*)].

A.T. Massey Coal Co. v. Holland, 472 F.3d 148, 167 (4th Cir. 2006).

Moreover, even if the PTO possessed *Chevron* interpretive authority over Section 120, which it does not, the changes the PTO has adopted in the Final Rules would represent unlawful rulemaking in violation of *Chevron* step one. Section 120 of the Patent Act clearly permits applicants to file an unlimited number of continuation applications that will relate back to the filing date of the original application. *See Sigmon Coal Co. v. Apfel*, 226 F.3d 291, 304 (4th Cir. 2000) ("The text makes this clear and unambiguous. Thus, we need not defer to the interpretation of the Social Security Administration . . . ."), *aff'd*, 534 U.S. 438 (2005).

Indeed, this is not the first time that the PTO has attempted to impose restrictions on continuation applications. The courts rebuffed a prior attempt, finding that the PTO exceeded the plain language of Section 120. *See Henriksen*, 399 F.2d at 254 ("under [§ 120 of the Patent Act], in view of its long-standing interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a

chain of copendency may be traced to obtain the benefit of the filing date of the earliest in a chain of copending applications, provided applicant meets all the other conditions of the statute"). The Final Rules cannot do what the courts have already told the PTO it is powerless to do.

In responding to comments, the PTO attempted to avoid *Henriksen*, characterizing the Final Rules as not imposing an absolute limit of two continuing applications. *See* Ex. A at 46756. However, the PTO's responses to comments demonstrate that the Final Rules will impose a *de facto* limit of two continuing applications because the PTO has indicated it will deny a petition for a third continuing application in almost all circumstances. *See id.* at 46769-77. This is not surprising given the PTO's purported reason for these rules—to reduce the PTO's workload by, among other things, reducing the number of continuing applications filed. In view of this, the PTO's petition requirement is illusory and is merely a thinly-veiled attempt to circumvent § 120 by imposing a limit on the number of continuing applications that may be filed.

In explaining this new petition and showing requirement in response to comments, the PTO has made clear that the "could not have" evidentiary burden in almost all cases precludes not just the grant of a petition, but the actual filing of a petition itself. *See* Ex. A at 46767-79. The "could not have" standard presents GSK with a Hobson's choice under the PTO's ethical rules, especially 37 C.F.R. § 10.85(a)(5), which 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, GSK's attorneys would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition. This conflict renders compliance with the PTO's new petition

requirement extremely difficult, if not impossible, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations as well as the "could not have" standard. As a result, the PTO's petition and showing represents a Hobson's choice and a regulatory trap.

In fact, GSK now finds itself confronted with that choice. As discussed earlier, GSK filed a third continuation in the '551 patent family, extinguishing the "one more" grace application. Knowles Decl. ¶¶ 40-42. That application discloses more compounds for treating diseases than it claims. *Id.* ¶¶ 38-39. Under the current rules, GSK would be entitled to file a continuation directed towards those unclaimed compounds. *Id.* ¶ 40. But under the Final Rules, because GSK *could have* presented claims directed to those compounds earlier, GSK is ethically shackled by § 10.85(a)(5) from submitting a petition. In sum, the Final Rules restrict GSK's ability to file continuing applications. *See* Knowles Decl. ¶¶ 40-44.

The Court should not tolerate the PTO's circumvention of Section 120's express language with this false "petition and showing" requirement, because the PTO cannot accomplish indirectly that which Congress has prohibited it from achieving directly. *See, e.g.*, *Concord v. FERC*, 955 F.2d 67, 71 n.2 (D.C. Cir. 1992); *Industrial Union Dep't, AFL-CIO v. Bingham*, 570 F.2d 965, 976 (D.C. Cir. 1977).

b. The Cases Upon Which The PTO Relies Support GSK's Position.

In responding to comments that it lacked statutory authority, the PTO attempted to justify its actions based on two Federal Circuit cases. *See* Ex. A at 46811 (citing *In re Bogese II*, 303 F.3d 1362 (Fed. Cir. 2002) and *Symbol Techs., Inc. v Lemelson Med., Educ. & Research Found.*,

277 F.3d 1361 (Fed. Cir. 2002) (*"Symbol I"*)).[6] The PTO asserts that these cases "suggest that the Office has the authority to place reasonable restrictions and requirements on the filing of continuing applications." *Id*. Nothing in those cases, however, authorizes the PTO to impose a bright-line restriction on continuation applications.

In fact, as the PTO correctly concedes, *Bogese II* and *Symbol* presented "extreme cases of prosecution laches."[7] *See* Ex. A at 46720. In *Bogese II*, the continuation application at issue was filed on January 23, 1995 and claimed the benefit of an application filed on June 14, 1978—nearly seventeen years earlier. 303 F.3d at 1363-65. Notably, because the application was originally filed before Congress implemented GATT, the continuation application would have had a lifetime of seventeen years from issuance while claiming benefit to an application filed nearly twenty years earlier.[8] Post-GATT implementation, the same application would have had a drastically reduced lifetime, if any, because, post-GATT, a patent's life extends twenty years from the filing date of the first application to which the continuation claims benefit. The pre-GATT situation rarely arises now and, under *Bogese II*, the PTO must deal with it on a case-by-case basis.

Symbol I reaffirmed that the doctrine of prosecution laches was good law. 277 F.3d at 1363-66. Later, the Federal Circuit ruled that the facts of that case justified finding that the

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[6] The PTO's comments refer to *Symbol I* and *Symbol II* using the same citation: 277 F.3d 1361. *Compare* Ex. A at 46720 (defining *Symbol I*) *with* Ex. A at 46811 (defining *Symbol II*). GSK understands the PTO to be referring to the one case, 277 F.3d 1361.

[7] "Prosecution laches renders a patent unenforceable if there has been an 'unreasonable and unexplained delay in prosecution even though the applicant complied with pertinent statutes and rules.'" *Mosaid Techs., Inc. v. Samsung Elecs. Co.*, 362 F. Supp. 2d 526, 551 (D.N.J. 2005).

[8] In the GATT implementing legislation, Congress changed the exclusivity period from seventeen years running from the date of issuance to twenty years from the filing date of the first application to which the patent claims priority. *See DiscoVision Assocs. v. Disc Mfg. Inc*., 42 U.S.P.Q. 2d 1749, 1756-57 n.11 (D. Del. 1997).

plaintiff had engaged in prosecution laches. *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378 (Fed. Cir. 2005) ("Symbol IV"). In *Symbol IV*, the patents at issue claimed the benefit of applications filed in 1954 and 1956—more than 40 years before the plaintiff asserted them in litigation. *Id*. at 1380-81. There, the Federal Circuit cautioned that applying prosecution laches too freely would run afoul of Section 120:

> There are legitimate grounds for refiling a patent application that should not normally be grounds for a holding of laches, and the ***doctrine should be used sparingly lest statutory provisions be unjustifiably vitiated***. The doctrine should be applied only in egregious cases of misuse of the statutory patent system.

Id. at 1385 (emphasis added). The Federal Circuit then provided examples of when an applicant may justifiably file continuation applications:

> Moreover, one might legitimately refile an application containing rejected claims in order to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses, although entitlement to an earlier filing date for any claimed subject matter may of course be necessary to avoid a statutory bar created by intervening events outlined in 35 U.S.C. §§ 102 and 103. One may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive.

Id. Despite the Federal Circuit's clear statement regarding the propriety of these reasons for filing continuation applications, the PTO has indicated it would not grant a petition based on such reasons. *See* Ex. A at 46772-77.

As these cases illustrate, in extreme cases of an applicant's delay, the PTO may reject an application under the doctrine of prosecution laches. *Symbol IV*, 422 F.3d at 1386 (emphasizing that only "an examination of the totality of the circumstances . . . may trigger laches"). But the cases do not grant the PTO the authority to innovate its own reforms based on a judicially created laches doctrine by issuing bright-line rules restricting applicants from filing more than two continuing applications (without a petition and showing). In other words, Congress did not

grant the PTO authority to restrict the filing of continuing applications, and the Federal Circuit cases at issue recognized no such authority. Thus, the Final Rules' restrictions on continuing applications contradict the express language of Section 120 and the very Federal Circuit precedent upon which the PTO relies.

c. The Final Rules' Restrictions On Continuing Applications Are Arbitrary And Capricious.

The PTO's obvious misperceptions of the limits of its statutory authority when crafting the Final Rules render its amendments to the continuing-application rules arbitrary and capricious. *See Prill v. NLRB*, 755 F.2d 941, 942 (D.C. Cir. 1985) (an agency's arbitrary and capricious action based on a misunderstanding of the law requires that the action be vacated and remanded for the agency to act consistent with the true bounds of the law). The PTO attempts to justify its new restrictions by invoking an administrative efficiency rationale. The PTO contends that restricting the number of continuation applications will reduce the strain on patent examiners and help to clear the PTO's backlog of pending patent applications. *See* Ex. A at 46752.

The PTO's backlog rationale is arbitrary and capricious, however, for it has not been adequately explained, ignores less-drastic and less-damaging alternatives to restricting abusive continuation applications, and is not supported by the PTO's own statistics on the number of third or subsequent continuation applications. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983) (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)). The PTO concedes that less than 2.7 percent of applications filed in fiscal year 2006 involved a third or subsequent continuing application or a second or subsequent RCE. *See* Ex. A at 46756. Hence, as the PTO admitted, it cannot meaningfully hope to reduce its backlog by revising the

continuing-application process. *Id.* ("The Office ***does not expect*** that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications." (emphasis added)). Thus, the backlog rationale is a red herring and cannot protect the PTO from a determination on judicial review that it acted arbitrarily and capriciously.

3. The Final Rules Are Beyond The PTO's Power Because They Retroactively Change The Legal Consequences Of Already Filed Continuing Applications And Patent Prosecution Strategies.

In *Bowen v. Georgetown University Hospital*, the Supreme Court 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***." 488 U.S. 204, 208 (1988) (emphasis added) (citations omitted); *see also Landgraf v. USI Film Prods.*, 511 U.S. 244, 272-73 (1994). Retroactivity applies when "the new provision attaches new legal consequences to events completed before its enactment." *Landgraf*, 511 U.S. at 270.

Here, Congress did not explicitly grant the PTO any retroactive rulemaking powers in 35 U.S.C. § 2(b)(2). Hence, the PTO lacks the power to engage in retroactive rulemaking under *Bowen* and its progeny. *See, e.g., Leland v. Fed. Ins. Admin.*, 934 F.2d 524, 527 (4th Cir. 1991). And it cannot be denied that the PTO's Final Rules apply retroactively in various respects. The PTO has made the decision to apply (with or without adjustments) its new rules to applications pending on November 1, 2007. These new rules will thus apply legal consequences to past events completed before the effective date where none attached before. For instance, under the Final Rules, as described above, GSK will be prevented from filing any additional continuing applications in the '551 patent application family.

The PTO argues that applying the Final Rules to existing applications is not retroactive because the agency is merely applying its new rules to pending applications, citing *Landgraf* and

cases involving the FCC where the D.C. Circuit held that applications for licenses did not create vested property rights. *See, e.g., Community Television Inc. v. FCC*, 216 F.3d 1133, 1143 (D.C. Cir. 2000). But that reasoning is flawed because the PTO ignores the fact that it is imposing new duties based on events that took place before the Rules' effective date. Also, conspicuously absent from the PTO's arguments is any reliance on cases relating to patent applications, which are property and not applications for the temporary use of the airwaves owned by the public. *See* Verified Am. Compl. ¶ 122.

Changes to the rules on patent applications mid-stream—while such applications are pending—are inherently retroactive, and thus unlawful under *Bowen*. Accordingly, all aspects of the Final Rules that apply to pending applications must be set aside and enjoined.

4. The PTO Lacks The Authority To Restrict RCEs.

Again, the PTO has exceeded its authority by restricting the ability of a patent applicant to request continued examination and applying that restriction retroactively. Amended § 1.114 restricts an applicant to only one RCE in a patent family (without the need for filing a petition and making a specified showing), which runs afoul of the express language of 35 U.S.C. § 132(b). Section 132(b) requires the Director to continue examining the application at the request of the applicant. Manbeck Decl. ¶ 34. In enacting § 132, Congress did not grant the Director the authority to restrict or the discretion to refuse to continue examining an application, after receiving an applicant's RCE. *Id.* ¶ 12. Accordingly, the PTO has overstepped its congressionally authorized powers in promulgating restrictions on RCEs.

5. The PTO Lacks The Authority To Impose Barriers That Restrict The Number Of Claims That Can Be Presented In A Patent Application.

The Final Rules also restrict GSK's ability to a limited number of claims, *i.e.*, a maximum of five independent and/or twenty-five total claims. This rule also applies

retroactively to certain applications. The PTO's attempt in the Final Rules to restrict the number of claims an applicant may file and the retroactive imposition of that limitation as to certain applications, exceeds the bounds of Congress' grant of authority as provided by 35 U.S.C. §§ 2, 111, 112. An application must include a specification that ends with one or more claims. *See* 35 U.S.C. §§ 111(a)(2), 112, ¶ 2. These sections do not remotely provide the Director with authority to limit the number of claims an applicant may file.

The PTO again invokes the administrative efficiency rationale in attempting to justify its new restrictions on the number of claims that may be presented in any application. The PTO's rationale is similarly arbitrary and capricious here because it is unsupported by data and insufficiently explained. In particular, the PTO failed to consider the dynamic effects that its rules restricting the number of claims would have on patent applications.

The Final Rules, when taken as a whole, will have the effect of precluding the filing of some perfectly meritorious claims to invention. Restricting rights to pursue valid claims under the Patent Act is inconsistent with the law and, therefore, not an available power to the PTO.

6. The ESD's Preexamination Search Requirement Is Vague And Does Not Put GSK On Sufficient Notice As To How To Comply.

Under new 37 C.F.R. § 1.75(b)(1), if an application contains more than five independent claims and/or twenty-five total claims, an applicant must file an ESD in compliance with new 37 C.F.R. § 1.265. Ex. A at 46836. Newly created § 1.265 sets forth the requirements of an ESD, including that the applicant perform a preexamination search. *Id*. at 46842. Under § 1.265(b), a preexamination search requires searching "U.S. patents and patent application publications, foreign patent documents and non-patent literature." *Id*. Neither this rule nor the comments, however, provides any boundaries on the scope of the search and, as a result, GSK cannot be certain about how to comply with this regulation. *See United States v. Lanier*, 520 U.S. 259, 266

(1997) (stating that 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 which libraries it must search. Certainly, the cost of searching could be quite large and the rule does not set forth an expense cap or limitation. The PTO has issued guidance documents, but those are not regulations and do not cure the vagueness of the ESD requirement. This ESD requirement will be imposed on several of GSK's pending applications as of November 1, 2007. Knowles Decl. ¶ 46.

D. GSK Will Be Irreparably Harmed If The Final Rules Go Into Effect.

GSK will be irreparably harmed if the PTO implements the Final Rules. First, GSK will be irreparably harmed by being required to comply with new patent regulations that are *ultra vires* because the PTO did not have the authority to promulgate them. Second, the Final Rules apply retroactively to pending applications. This will diminish GSK's patent rights in its inventions by restricting its ability to file continuing applications and a sufficient number of claims for inventions that were discovered and developed based on the current, well-established regulations. GSK has many pending application families with two or more continuing applications and/or one RCE that will be governed by the "could not have been submitted" standard. Knowles Decl. ¶¶ 20-21. GSK also has pending applications that contain a sufficient number of claims to trigger the ESD requirement. *Id.* ¶ 22. Through retroactive application, the Final Rules will force GSK to accept less protection than it is entitled to under the law and under the well-established rules in place at the time these applications were filed, causing irreparable injury to GSK.

GSK will also be irreparably harmed by its inability to comply with the Final Rules. New § 1.265, which identifies the ESD's requirements, is vague and incomprehensible. GSK remains uncertain how it will identify a viable path to comply with this regulation, if enacted. Knowles Decl. ¶¶ 45-48.

Because the Final Rules truncate GSK's patent rights, they put substantial investment capital at risk. If not preliminarily enjoined, if the Final Rules are ultimately vacated as illegal and vague, it will almost certainly be too late to save patent rights covering medical inventions that cannot proceed to market without strong protection. The drugs will be lost to both GSK and the public. Such situations constitute irreparable harm. *See Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 361 (4th Cir. 1991) (finding irreparable harm where an aggrieved party could not later recover monetary damages if a governmental action is later found to be unconstitutional or unlawful). Courts have found irreparable injury most often when damages are not susceptible of exact proof or are not recoverable. *See Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994) ("irreparable injury is suffered when monetary damages are difficult to ascertain or are inadequate"); *Phillips v. Crown Cent. Petroleum Corp.*, 602 F.2d 616, 630 (4th Cir. 1970). GSK's irreparable harm is even more evident because it likely cannot sue the federal government to reinstate its lost patent protection.

E. The Balance Of Hardships Weighs Decidedly In GSK's Favor.

In contrast to the irreparable harm GSK will experience, the PTO will suffer little, if any, prejudice should this Court stay implementation of the Final Rules pending a final resolution of the merits. Temporarily delaying the implementation of the Final Rules would maintain the status quo by leaving the PTO's current application examination process in place. That approach is well-established and understood, as the PTO and applicants have used that approach for over

fifty years. On the other hand, while the Final Rules now cast a pall over patenting decisions and business-investment decisions, the full force of the Final Rules has yet to be felt. Nevertheless, the Final Rules immediately require, in effect, that GSK, and other applicants, make significant and radical changes in how they prosecute patent applications to account for the arbitrary and illegal application and claim limits erected in the Final Rules.

Further, the PTO admits it does not have much to gain from this rulemaking. The PTO's rationale in adopting the Final Rules—improving efficiency by reducing the workload for its examining corps—actually supports enjoining the rules. The PTO, itself, admitted that it "does not expect that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications." Ex. A at 46756. Moreover, on October 10, 2007, the PTO waived and/or delayed the effect of certain provisions of the Final Rules regarding pending applications. *See* Ex. D. In light of the PTO's admission and its waiver and/or delay of certain provisions, the harm to the PTO in maintaining the status quo is shown to be minimal.

F. The Public's Interest In Promoting Innovation Outweighs Any Marginal Benefit Gained By The Final Rules.

The public interest in a strong, predictable, and stable patent system is undeniable. The patent system is vital to encouraging innovation. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) ("We have long acknowledged the importance of the patent system in encouraging innovation."). GSK spends billions of dollars researching and developing new and improved medicines. GSK depends on strong patent protection to recoup its massive expenditures, while continuing to innovate and bring new medicines to market. *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) ("The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to

exclude."). Indeed, "the patent system provides incentive to the innovative drug companies to continue costly development efforts [such] that the[re is a] significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents . . . ." *Sanofi-Synthelabo*, 470 F.3d at 1383-84 (citations omitted). The public unquestionably benefits from these innovations, which the patent system makes possible. In short, the public interest favors maintaining the status quo until final resolution of the merits.

IV. CONCLUSION

For the foregoing reasons, GSK respectfully submits that the Court should enjoin enactment of the Final Rules until it issues a final ruling on the merits.

Date: October 15, 2007

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

Pursuant to Rules 5 and 65(b), I hereby certify that a true copy of the following motions and papers was filed electronically this 15th day of October 2007 using the CM/ECF system, which will send notification by electronic means to the following counsel of record:

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PLEADINGS AND PAPERS SERVED:

(i) Notice of Hearing;

(ii) Motion for a Temporary Restraining Order and Preliminary Injunction;

(iii) Memorandum in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction (attaching the following declarations);

(iv) Declaration of Sherry M. Knowles in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction;

(v) Declaration of Harry F. Manbeck, Jr.; and

(vi) Proposed Order Granting Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction

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