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

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED, d/b/a/ GLAXOSMITHKLINE, Plaintiffs, v. JON W. DUDAS, in his official capacity as Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and UNITED STATES PATENT AND TRADEMARK OFFICE, Defendants.	)	Civil Action No. 1:07cv1008 (JCC/TRJ) [Consolidated with No. 1:07cv846]

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively the "USPTO" or the "Office") respectfully submit this brief in opposition to the Motion for a Temporary Restraining Order and Preliminary Injunction filed by Plaintiffs SmithKline Beecham Corp., d/b/a GlaxoSmithKline, SmithKline Beecham PLC, and Glaxo Group Limited, d/b/a GlaxoSmithKline (collectively "Plaintiffs" or "GSK").

INTRODUCTION

On November 1, 2007, the USPTO expects to implement rules aimed to improve the quality and efficiency of patent application examination, lead to higher quality patents, and reduce a growing backlog of applications that is crippling the Office. The rules are the product of extensive planning and development. In January 2006, the USPTO proposed new rules in the Federal Register. The USPTO then spent more than a year holding "town hall" meetings to inform the public of the new rules, analyzing more than 500 public comments, and making adjustments to address the public's concerns. The USPTO published its final rules on August 21, 2007. Since then, the Office has spent millions of dollars gearing up to implement the rules by training more than 6,300 employees, restructuring its information technology systems, and preparing the public for compliance.

Now, just days before the rules are to go into effect, Plaintiffs want this Court to bring them to a halt. There is no justification for the extraordinary remedy of a preliminary injunction.

First, Plaintiffs will not be irreparably harmed during the pendency of this litigation.[1]

[1] The USPTO does not expect prolonged litigation of this case. At present, the USPTO has agreed to an expedited briefing schedule in Tafas v. Dudas, 1:07cv846 (JCC/TRJ), in lieu of Mr. Tafas seeking a preliminary injunction. See Tafas, Dkt. Nos. 16, 23. Plaintiffs suggest in their Proposed Order that the Court should allow them to join the Tafas briefing schedule. See Proposed Order, pp. 4-5. Although the USPTO is prepared to proceed

While Plaintiffs, in the long run, may need to adjust their business strategy, they will not immediately lose any patent rights and will still be able to seek patents for the inventions they have disclosed in their pending applications.

Second, due in part to the length of time the Plaintiffs chose to wait before coming into Court, the USPTO would suffer severe harm if the Court were to enjoin the rules on the eve of their implementation. The USPTO has already spent millions of dollars preparing its employees, its information technology systems, and the public for the rules to go into effect on November 1. Postponing their implementation to some indefinite date would wreak administrative havoc on the agency, require significant additional expenditures, and breed confusion among the public. The balance of the harms thus weighs in favor of the USPTO and against a preliminary injunction.

Third, Plaintiffs have not established a likelihood of success on the merits of their claims under the Administrative Procedures Act ("APA"), 5 U.S.C. §§ 701-706. The USPTO clearly has authority to promulgate the new rules. See 35 U.S.C. § 2(b)(2)(A), (C) & (D). Because the rules are consistent with the Patent Act and reasonable, they are entitled to Chevron deference. Moreover, as the nearly 10,000-page administrative record attests,[2] the USPTO hardly acted in an

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expeditiously, the USPTO objects to the suggestion that Plaintiffs, who filed their lawsuit nearly two months after Mr. Tafas and would not agree to forego a preliminary injunction motion, should be entitled to the expedited briefing schedule that was the result of an arms-length negotiation. Moreover, the USPTO is entitled to sixty days – to December, 10, 2007 – to respond to GSK's Verified Amended Complaint. See Fed. R. Civ. P. 12(a)(3). To the extent the Court wishes to have the two cases proceed in tandem, the USPTO respectfully requests that the Court set a lengthier briefing schedule for both cases, so that the USPTO will have an adequate opportunity to respond to both the GSK and Tafas briefs, as well as anticipated amicus briefs. Otherwise, GSK should be required to await the outcome of the summary judgment briefing in Tafas and, thereafter, raise any additional claims that have not yet been resolved.

[2] The USPTO filed the administrative record for these rules in connection with the Tafas case, 1:07cv846. Dkt. Nos. 21, 22. For ease of reference, the USPTO has attached the

arbitrary or capricious manner in enacting these rules. Nor did the USPTO promulgate retroactive rules. Finally, Plaintiffs' contention that one of the final rules is vague is meritless for numerous reasons.

Fourth, the public would be harmed if the Court were to enjoin the final rules, which are, after all, aimed at benefitting the public by allowing the USPTO to process patent applications more efficiently. A preliminary injunction would also punish the many practitioners who have responsibly taken steps to prepare for the rules to go into effect on November 1, 2007.

For all of these reasons, the Court should deny the Plaintiffs' eleventh-hour attempt to derail these rules. The rules represent a careful and lawful attempt by a federal agency to improve its own efficiency for the good of the public. There is no basis for an injunction.[3]

BACKGROUND

I. PATENT APPLICATION PROCESS

An inventor who seeks to protect an invention may file a patent application with the USPTO. The first application the inventor files for a given invention is known as the **"parent"** (or "initial") application. A patent application is, essentially, a draft patent. It contains two primary parts: (1) a **"specification"**; and (2) one or more **"claims."** The specification describes the invention for which a patent is sought, as well as how to make and use the invention. See 35 U.S.C. § 112, first paragraph. The claims identify what the applicant regards as his invention,

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portions of the administrative record on which it relies in this brief at Exhibit 1. Specific pages of the administrative record are designated as "A___."

[3] The USPTO has elected not to challenge this Court's jurisdiction over Plaintiffs' suit at the preliminary injunction stage. The USPTO may, however, raise such arguments at a later time. See Fed. R. Civ. P. 12(h)(1).

i.e., the scope of legal protection the applicant believes his or her invention is entitled to receive. See id., second paragraph; In re Vamco Mach. & Tool, Inc., 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985) ("[C]laims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of lands by metes and bounds in a deed").

A patent claim may be in **"independent"** or **"dependent**" form. An independent claim, as the name suggests, stands on its own, reciting all the limitations of the invention. See 35 U.S.C. § 112, third paragraph. By contrast, a dependent claim incorporates the limitations of the independent claim and recites one or more further limitations of the invention.[4] See id., fourth paragraph; see also U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure ("MPEP") § 608.01(n) (8th ed. 2001, rev. Aug. 2006).

When a patent applicant files an application with the USPTO, a patent examiner determines whether the claimed invention meets the statutory requirements found in Title 35 of the United States Code. See 35 U.S.C. §§ 101, 102, 103 & 112. If the examiner finds that a claim does not comply with the statutory requirements, the examiner will reject the claim and issue an **"Office action"** setting forth the grounds for rejection. 35 U.S.C. § 132(a); 37 C.F.R. § 1.104(a) (2006). In response, the applicant may (i) **"amend"** the claims; (ii) argue against the rejection; or (iii) present evidence to show why the claimed invention is believed to be patentable. 37 C.F.R. § 1.111 (2006). The examiner may then "allow"—that is, authorize for patenting—some or all of

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[4] For example, Claims 1 and 2 below are independent claims; Claim 3 is a dependent claim.

1. An automobile comprising: a chassis; an engine; and four wheels.
2. An automobile comprising: a chassis; an engine; four wheels; and four doors.
3. The automobile of claim 1 wherein the engine is an internal-combustion engine.

For purposes of this motion, the Court need not concern itself with other types of claims.

the claims or issue another rejection. The back-and-forth exchange that occurs between an applicant and an examiner is commonly referred to as the **"prosecution"** of an application.

Upon receipt of a final rejection, an applicant has four choices[5]: (1) appeal to the Board of Patent Appeals and Interferences (**"Board"**) and from there to the Federal Circuit, 35 U.S.C. §§ 134, 141; (2) file a "**request for continued examination**" of the application, which typically extends examination of the application for two more rounds with the examiner, 35 U.S.C. § 132(b); 37 C.F.R. § 1.114 (2006); (3) file a **"continuation"** (or a "continuation-in-part") application of the initial application, 35 U.S.C. § 120; or (4) file an after final "**amendment**," 37 C.F.R. §§ 1.116, 1.121 (2006).[6]

An applicant files a "continuation" application when the applicant wants to amend the claims, offer additional evidence on patentability, or further argue why the claims are patentable. A continuation uses the same specification as the pending parent application, must name at least one of the same inventors as the parent application, and enjoys the benefit of the filing date (a.k.a. **"priority date"**) of the parent application. See 35 U.S.C. § 120; MPEP § 201.07.

Sometimes, an applicant may disclose and claim more than one independent or distinct invention in the initial application. In such cases, an examiner may require the applicant to separate the multiple independent or distinct inventions into one or more **"divisional"** applications, each claiming only a single invention. See 35 U.S.C. § 121. This is called a **"restriction requirement."** In response to a restriction requirement, the applicant must choose

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[5] The USPTO inadvertently omitted the fourth of these options in the "Background" of its Memorandum in Support of Defendants' Motion to Dismiss in Tafas. Tafas, Dkt. No. 18.

[6] The applicant need not await a final rejection to file a continuation or continuation-in-part application or an amendment.

one of his or her claimed inventions to prosecute in the initial application and is authorized to file separate "divisional" applications to protect each of the other inventions. Like a continuation application, a divisional application claims the priority date of the parent application.[7] See id.; MPEP § 201.06.

II. HISTORY OF THE FINAL RULES FOR CONTINUATION AND CLAIMS PRACTICE

Over the past decade, the growing number of continuing applications, as well as the increasing number and complexity of claims in patent applications, have crippled the Office's ability to examine newly-filed applications. See Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule, 72 Fed. Reg. 46716, 46718 (Aug. 21, 2007) ("Final Rules") (Ex. 2). Indeed, as of 2006, the Office's backlog of unexamined applications stood at 701,147 applications. Id. at 46790. The growing number of continuing applications are attributable to a variety of factors, including: (1) applicants, such as Plaintiffs, using the availability of continuing applications to delay the conclusion of examination until they assess the commercial viability of inventions that may fall within the scope of yet-to-be-presented claims (2) applicants filing deficient initial applications and relying on the availability of an endless stream of continuing applications to work out issues of patentability; and (3) applicants filing literal or machine-translated documents as patent applications and using continuing applications to correct avoidable mistakes. See Ex. 2 at 46719.

Consequently, in January 2006, the USPTO proposed new rules for filing continuing

[7] Collectively, a "continuation," a "continuation-in-part," and a "divisional" are commonly referred to as **"continuing applications."** See 37 C.F.R. § 1.53(b) (2006).

applications and for presenting claims. See Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and Applications Concerning Patentably Indistinct Claims, 71 Fed. Reg. 48 (Jan. 3, 2006); Changes to Practice for the Examination of Claims in Patent Applications, 71 Fed. Reg. 61 (Jan. 3, 2006) (collectively "Proposed Rules") (Ex. 3). The USPTO solicited public comments to the Proposed Rules and provided a four month comment period. Id. at 46717. The USPTO received more than 500 written comments. Id. It then spent more than a year carefully analyzing and considering the feedback. Id. After modifying the Proposed Rules to respond to some of the public's concerns, the USPTO published its Final Rules on August 21, 2007. See generally Ex. 2.

III. OVERVIEW OF FINAL RULES REGARDING CONTINUATION AND CLAIMS PRACTICE

In promulgating the Final Rules, the USPTO sought to enact reasonable rules that would increase application quality, reduce the backlog, and improve examination efficiency, while also allowing the public ample opportunity to claim their inventions. Id. at 46719.

A. Final Rules 78 and 114 Permit An Applicant to File Two Continuation or Continuation-In-Part Applications and One Request for Continued Examination Without a Petition and Showing.

The Final Rules allow an applicant to file two continuation or continuation-in-part applications, plus a single request for continued examination, after an initial application as a matter of right (i.e., a total of three filings after an initial application). See Ex. 2 at 46718; see also 37 C.F.R. § 1.78(d)(1)(i), (ii), & (iii) (**"Final Rule 78"**); 37 C.F.R. § 1.114(f) (**"Final Rule 114"**). If an applicant wants to engage in more prosecution at the examiner level, the Final Rules allow an applicant to file any third or subsequent continuation or continuation-in-part application and any second or subsequent request for continued examination with a **"petition and showing"**

of need. See Ex. 2 at 46719; see also 37 C.F.R. §§ 1.78(d)(1)(vi), 1.114(g). That is, to justify a further filing beyond three, an applicant must explain why the argument, amendment, or evidence could not have been presented in one of the previously-filed applications. Final Rules 78(d)(1) and 114(g) apply to all initial and continuing applications filed on or after November 1, 2007. See Ex. 2 at 46716, 46736.

When an applicant files an application claiming more than one invention, the USPTO may subject that application to a restriction requirement, as explained above. See 35 U.S.C. § 121. Under the Final Rules, an applicant who claimed multiple inventions in a single application may suggest a restriction requirement to the USPTO. See Ex. 2 at 46726; 37 C.F.R. § 1.142(c) ("Final Rule 142"). If the examiner accepts the **"suggested restriction requirement"** or issues one of his or her own, the applicant may file a divisional application for each invention. Each divisional application is treated under the Final Rules as the initial application in a new application family, thereby enabling an applicant to file two continuation applications, plus a single request for continued examination, in the family without any petition and showing. See Ex. 2 at 46732; 37 C.F.R. § 1.78(d)(1)(ii) & (iii).

B. Final Rule 75 Permits An Applicant to File Five Independent Claims and Twenty-five Total Claims in Any Application Without the Examination Support Document of Final Rule 265.

The Final Rules permit an applicant to present a total of **five independent claims and twenty-five total claims** for examination without providing any further information about the claims. See Ex. 2 at 46721; see also 37 C.F.R. § 1.75(b)(1) (**"Final Rule 75,"** a.k.a **"5/25 Rule"**). If an applicant wants to present more than five independent claims or more than twenty-five total claims, then Final Rule 75 requires the applicant to provide an **"examination support**

document," which must contain information about the claims, before the issuance of a first Office action on the merits in the application. Ex. 2 at 46721; 37 C.F.R. § 1.75(b)(1). An examination support document is intended to assist the examiner in determining the patentability of the claimed invention. Ex. 2 at 46721. The requirements of an examination support document are set out in 37 C.F.R. § 1.265 (**"Final Rule 265**"), see Ex. 2 at 46842, and in guidance issued by the USPTO. See generally Faile Decl. (Ex. 4). In light of the two continuation or continuation-in-part applications that an applicant may file after the initial application, an applicant ultimately may present fifteen independent claims and seventy-five total claims covering each invention without filing any examination support document. Id. at 46718, 46721. Final Rule 75 applies to all applications filed on or after November 1, 2007, and all pending applications for which a first Office action on the merits was not mailed before November 1, 2007. Id. at 46716, 46728.

C. Plaintiffs' Prosecution Strategy

In their papers, Plaintiffs are unabashed about their typical prosecution strategy: "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." Memorandum in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction ("Pl. Mem.") at 5. Plaintiffs thus initially describe a broad array of inventions (e.g., compounds, methods of using the compounds, and processes for making the compounds) in their parent application, but delay in actually claiming these inventions until it is advantageous for them to do so in continuing applications. See id. at 5-6. After putting a big "stake in the ground," Plaintiffs use their initial application as a launch pad from which to later obtain patents on numerous inventions. Id. at 6.

Plaintiffs exemplify this strategy in the application family that has so far yielded U.S. Patent No. 7,235,551 ("the '551 patent"). Id. at 5. On March 2, 2000, Plaintiffs filed a provisional patent application ("Provisional Application"). LeGuyader Decl. (Ex. 5) at ¶ 5. One year later, Plaintiffs filed an international application ("International Application").[8] Id. at ¶ 6. In 2002, Plaintiffs' International Application entered the United States as U.S. Application No. 10/220,103 ("Parent Application") under 35 U.S.C. § 371. Id. at ¶ 7. Plaintiffs' Parent Application claims the benefit of the filing date of the Provisional Application. Id. It eventually issued as the '551 patent on June 26, 2007. Id. at ¶ 9.

On December 20, 2006, while their Parent Application was still pending, Plaintiffs filed two continuation applications, both claiming the benefit of the filing dates of the Parent Application and the Provisional Application. Id. at ¶¶ 10, 14. Ten months later, on October 11, 2007, Plaintiffs filed a third continuation application, claiming the benefit of the filing dates of one of the earlier filed continuation applications, the Parent Application, and the Provisional Application. Id. at ¶ 18. Thus, Plaintiffs currently have three continuation applications pending in the '551 family.

While this type of strategy may be advantageous to Plaintiffs and others, its effects on the efficiency of the USPTO are profound. The Final Rules are intended, in large part, to remedy these ill-effects.

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[8] The Patent Cooperation Treaty ("PCT"), Jan. 24, 1978, 28 U.S.T. 7645, enables an applicant to file one application in English in the USPTO and have that application acknowledged as a regular national patent application in as many Contracting States to the PCT as the applicant designates.

PRELIMINARY INJUNCTION STANDARD

Plaintiffs' motion for a preliminary injunction must be denied. Because a preliminary injunction is an "extraordinary remedy," to be applied in "limited circumstances," the party seeking it bears a substantial burden of proof. Direx Israel, Ltd. v. Breakthrough Med. Corp., 952 F.2d 802, 811 (4th Cir. 1991). The Fourth Circuit applies a four-part test to evaluate whether a preliminary injunction should issue. See Direx, 952 F.2d at 812. The factors are: (1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied, (2) the likelihood of harm to the defendant if the requested relief is granted, (3) the likelihood that the plaintiff will succeed on the merits, and (4) the public interest. See id. The plaintiff "bears the burden of establishing that each of these factors supports granting of the injunction." Id.

In the Fourth Circuit, "[t]he irreparable harm to the plaintiff and the harm to the defendant are the two most important factors." Id. Thus, the Court begins its analysis not with the likelihood of success on the merits, but rather by balancing the hardship to the parties. See Direx, 952 F.2d at 813; Blackwelder Furniture Co. of Statesville, Inc. v. Seilig Mfg. Co., 550 F.2d 189, 194-95 (4th Cir. 1977). Where, as here, the balance of the hardships tips away from the plaintiff, a stronger showing of likelihood of success on the merits is required. Direx, 952 F.2d at 813.

The USPTO does not dispute that this case is properly appealed to the Federal Circuit, which recognizes that "the general considerations underlying the grant or denial of a preliminary injunction do not vary significantly among the circuits." Mikohn Gaming Corp. v. Acres Gaming, Inc., 165 F.3d 891, 894 (Fed. Cir. 1998). Generally, the Federal Circuit applies the procedural law of the regional circuit in which the case originated – hence, Fourth Circuit law. Id. However, when issues underlying a preliminary injunction motion are "unique to patent law," the Federal

Circuit applies its own law to procedural issues. Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1329 n.1 (Fed. Cir. 2001); Mikohn, 165 F.3d at 894 ("[W]e give dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues").

To the extent Plaintiffs' motion raises specific patent law issues, the Federal Circuit requires Plaintiffs to show "(1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest." Amazon.com, Inc. v. Barnesandnoble.com Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). Under either the Fourth or the Federal Circuit standards, Plaintiffs are not entitled to a preliminary injunction for the reasons stated herein.

ARGUMENT

I. PLAINTIFFS WILL NOT SUFFER IRREPARABLE HARM DURING THE PENDENCY OF THIS ACTION.

In order to satisfy the first prong of the preliminary injunction analysis, Plaintiffs must make a "clear showing" that irreparable harm will immediately accrue to them unless the Final Rules are enjoined. Direx, 952 F.2d at 812; see also Scotts Co. v. United Indus. Corp., 315 F.3d 264, 271 (4th Cir. 2002) (holding that the plaintiff must make a "strong showing" of irreparable harm). Such harm "must be neither remote nor speculative, but actual and imminent." See Direx, 952 F.2d at 812 (internal quotation marks omitted); see also Wisconsin Gas Co. v. Fed. Energy Reg. Comm'n, 758 F.2d 669, 674 (D.C. Cir. 1985) ("[T]he injury must be both certain and great; it must be actual and not theoretical.").

Significantly, several courts have held that the alleged costs and difficulties associated with complying with a government regulation ordinarily do not constitute "irreparable harm" for purposes of obtaining preliminary injunctive relief. See, e.g., Freedom Holdings, Inc. v. Spitzer,

408 F.3d 112, 115 (2d Cir. 2005) (providing that ordinary costs to comply with government regulation are typically insufficient to constitute irreparable harm); Am. Hosp. Ass'n v. Harris, 625 F.2d 1328, 1331 (7th Cir. 1980) ("Injury resulting from attempted compliance with government regulation ordinarily is not irreparable harm."); A.O. Smith Corp. v. FTC, 530 F.2d 515, 527 (3d Cir. 1976) ("Any time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone," qualifies as irreparable harm).

Here, Plaintiffs principally allege that they will suffer three types of harm if the Court does not preliminarily enjoin the Final Rules.[9] Each of these allegations either is factually or legally incorrect or does not give rise to cognizable irreparable harm.

Plaintiffs first claim that the Final Rules 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." Pl. Mem. at 27. As an initial matter, Plaintiffs fail to specifically allege the existence of any continuing applications that they intend to file during the pendency of this litigation – an omission that itself calls into doubt their alleged harm. Even if Plaintiffs actually intend to pursue patent protection for their disclosed but unclaimed inventions, however, there is nothing stopping them from claiming their inventions right now. Indeed, as Declarant Knowles has admitted, "GSK 'could have' filed claims earlier." Pl. Ex. B at ¶ 44; Pl. Mem. at 20 ("GSK

[9] In view of the principles just articulated, Plaintiffs' first alleged harm, that they will be "irreparably harmed by being required to comply with new patent regulations that are ultra vires," merits no discussion. Pl. Mem. at 27.

could have presented claims directed to these compounds earlier").

Plaintiffs' "exemplar" application family illustrates the point. See PI Memo at 5 (citing the '551 patent) & Pl. Ex. B, Knowles Decl.). Plaintiffs identify the '551 patent as the head of an application family where – in keeping with their strategy of intentionally delaying the claiming of all disclosed inventions – Plaintiffs initially disclosed more inventions than they claimed. Id. at 6; see also Pl. Ex. B at ¶ 34. There are several procedural options available to Plaintiffs to claim the remaining inventions disclosed in the '551 application family after the Final Rules go into effect:

1. Plaintiffs may avoid the need to file continuation applications all together by filing amendments to add claims covering their disclosed, unclaimed inventions in any of their three pending continuation applications in the '551 application family. Given that none of the three continuation applications have received even a first Office action, see Ex. 5, LeGuyader Dec. at ¶¶ 13, 17 & 21, and given that the time from application filing to a first Office action in the Technology Center where Plaintiffs' application family will be examined is 21.3 months, see id. at ¶ 22, Plaintiffs will have ample time to amend their claims. They may do so before they receive their first Office action, 37 C.F.R. § 1.115, in response to their first Office action, id. § 1.111, and, if permitted, after they receive a final Office action, id. § 1.116. These opportunities will take Plaintiffs well past the time this litigation is expected to be pending.

2. If Plaintiffs wish to amend any of their three pending continuation applications by adding claims drawn to independent or distinct inventions, they may present a suggested restriction requirement ("SRR") to the Office. See Ex. 2 at 46728; 37 C.F.R. § 1.142(c). If the USPTO accepts the SRR, Plaintiffs will be free to file separate divisional applications for each of

the restricted inventions pursuant to 35 U.S.C. § 121.[10] Then, in each of those divisional applications, Plaintiffs will be entitled to file two continuation applications and one request for continued examination without presenting any petition and showing. See Ex. 2 at 46732; 37 C.F.R. § 1.78(d)(1)(ii) & (iii). Thus, if Plaintiffs have six or more independent and distinct inventions, as alleged, see Pl. Mem. at 6; Pl. Ex. B at ¶ 34, they could file up to eighteen or more applications.

3. If either of the first two opportunities somehow (albeit inconceivably) would not suffice to enable Plaintiffs to claim all of their inventions, they may obtain additional continuation applications or requests for continued examination through the Final Rule 78(d)(1)(vi) or Final Rule 114(g) petition process, respectively. If Plaintiffs' petition is denied, they will have a final agency action and may then pursue their rights through an APA action in this very Court. See Am. Hosp. Ass'n, 625 F.2d at 1331 ("[I]njury resulting from attempted compliance with government regulation ordinarily is not irreparable harm.").

Given the availability of these significant procedural options, Plaintiffs cannot establish that they would suffer any concrete harm to their future patent rights – much less that such harm would be irreparable – if the Final Rules go into effect on November 1, 2007. Moreover, in view of the first two procedural options, which allow Plaintiffs to claim their inventions without having to petition the USPTO under Final Rule 78(d)(1)(vi) or 114(g), Declarant Knowles' concern about potentially violating ethical rules when filing such petitions is a red herring. Pl. Ex. B at ¶ 44.

Plaintiffs next assert that they will be harmed when they are "forced to comply with the

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[10] The standard by which the USPTO will evaluate an SRR is the same as the standard for a patent examiner herself to make a restriction requirement. See Ex. 2 at 46747.

[examination support document's ("ESD's")] incomprehensibly vague preexamination search requirement." Pl. Mem. at 2, 28. As noted above, "injury resulting from attempted compliance with government regulation ordinarily is not irreparable harm." Am. Hosp. Ass'n, 625 F.2d at 1331. Furthermore, Plaintiffs grossly exaggerate their inability to comply with Final Rule 265. As explained in the Faile declaration, the USPTO has already addressed each and every one of the issues that Declarant Knowles finds confusing through the Final Rules themselves or through public guidance, available on the USPTO's website.[11] See Ex. 4, Faile Decl. at ¶ 23 (offering point-by-point rebuttal of Knowles declaration, ¶ 47). There is thus no reason why Plaintiffs should not be able to comply with Final Rule 265.

In any event, Plaintiffs will not have to file any ESDs on November 1, 2007, and, depending on when their applications are examined, may never have to file one before the Court decides the merits of this case. The Final Rules do not require an ESD to be immediately filed on November 1, 2007 for currently pending applications, but rather indicate that a notice will first be sent with a two month response deadline (extendable up to four months), when an ESD is necessary. See Ex. 2 at 46836, 46842; 37 C.F.R. §§ 1.75(b)(1), 1.136. Such a notice will not be sent until a particular application is brought up for examination in due course. See Ex. 4, Faile Decl. at Ex. B, question F19 at 31. Moreover, if applicants have followed their alleged typical strategy of disclosing multiple inventions in pending applications, they could present a suggested restriction requirement. See Ex. 2 at 46728. If the USPTO adopts the SRR, Plaintiffs will be free to file separate divisional applications for each invention, each of which may contain up to five

[11] The USPTO informed the public that it would provide guidance on its website when it published the Final Rules. See Ex. 2 at 46741, 46800.

independent and twenty-five total claims without filing an ESD. See Ex. 2 at 46728.

Third, Plaintiffs allege that since they "will not know whether the Final Rules will be ultimately stricken and whether they 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." Id. at 2 (emphasis added). As noted above, however, "irreparable harm must be neither remote nor speculative, but actual and imminent." See Direx, 952 F.2d at 812 (internal quotation marks omitted); Wisconsin Gas, 758 F.2d at 674 ("[T]he injury must be both certain and great; it must be actual and not theoretical."). Moreover, "[a]ny time a corporation complies with a government regulation that requires corporation action, it spends money and loses profits; yet it could hardly be contended that proof of such an injury, alone," qualifies as irreparable harm. A.O. Smith, 530 F.2d at 527. That Plaintiffs, in the long run, "may be" required to adjust their strategic behavior because they will no longer be able to engage in the dilatory prosecution strategy they have used to date, is simply too speculative and generalized to constitute immediate irreparable harm.

In the end, Plaintiffs have not established that any certain, concrete harm will accrue to them if the Final Rules go into effect on November 1, 2007, as planned.

II. THE USPTO WILL SUFFER CONSIDERABLY MORE HARM THAN PLAINTIFFS IF THE COURT ISSUES A PRELIMINARY INJUNCTION.

If an injunction issues preventing the USPTO from implementing the Final Rules on November 1, 2007, the USPTO will suffer immediate concrete harm in a variety of ways, the tangible financial cost of which will be in the millions of dollars and the intangible quality cost of which is immeasurable. This concrete harm far outweighs the speculative harm Plaintiffs allege

they will suffer. Indeed, as explained above, Plaintiffs have multiple procedural avenues available to obviate their harm. The USPTO does not. Had Plaintiffs filed their lawsuit and moved the Court earlier for a preliminary injunction, the USPTO may have been able to avoid some of these costs. At this point, however, it is too late.[12]

First, the USPTO has spent more than 25,000 hours preparing its employees for implementation of the Final Rules on November 1, 2007.[13] Young Decl. (Ex. 6) at ¶ 13. It has developed extensive written training materials about the Final Rules. Id. at ¶¶ 6, 7 & 8. It has also offered live and computer-based classes to teach patent examiners and patent management about the Final Rules. Id. at ¶¶ 9,10. Specifically, for each of the USPTO's 5477 patent examiners, 432 managers, and 24 directors, the USPTO has provided an Overview Training class (1 hour with accompanying slides) and a Detailed Training class (3 hours with accompanying handouts). Id. at ¶ 13. Additionally, the USPTO offered training on the Final Rules to technical support staff (3 hours with accompanying slides), id. at ¶ 11, and offered specialized training on ESDs to select USPTO managers (2 hours with accompanying slides and handouts), id. at ¶ 12. Thus, by November 1, the USPTO will have trained 6,300 USPTO employees for a total of 25,280 hours, translating to a loss of revenue of more than $3.1 million. Id. at ¶¶ 14, 15, 16 &17. If the USPTO cannot implement the Final Rules on November 1 and the Court ultimately upholds

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[12] Cf. Quince Orchard Valley Citizens Ass'n, Inc. v. Hodel, 872 F.2d 75, 80 (4th Cir. 1989) (affirming denial of preliminary injunction and remarking that "[e]quity demands that those who would challenge the legal sufficiency of administrative decisions concerning time sensitive public construction projects do so with haste and dispatch. To require any less could well result in costly disruptions of ongoing public planning and construction.").

[13] The USPTO has separately spent additional hours preparing the public for the Final Rules by holding seminars and providing educational materials on its website. See, e.g., Ex. 4, Faile Decl at ¶¶ 11-14 & Exs. A, B, & C.

the Final Rules months later, as the USPTO expects, the agency will be forced to spend millions more dollars re-training its 6,300 employees, causing a further loss of revenue.

Next, the USPTO would suffer a critical problem with the computer systems used to electronically track and manage patent application filings and the patent examination process. The "Patent Application Location Monitoring" ("PALM") computer system reports and captures all information about each patent application in the USPTO from filing to issuance or abandonment and serves as the exclusive way for both examiners and applicants to monitor filings. Breneman Decl. (Ex. 7) at ¶ 3. The USPTO has modified PALM in six structural ways in anticipation of the Final Rules. Id. at ¶ 4. These modifications have taken fifty USPTO employees more than four months to make and have cost the agency more than $1.6 million. Id. at ¶ 5. The modifications are programmed to take effect on November 1 and cannot simply be "turned off" or "undone" if the USPTO is preliminarily enjoined from implementing the Final Rules. Id. at ¶ 6. Instead, the USPTO will have to enter a "stand down" period and engage in "work arounds" to be able to use the PALM system. Id. The USPTO will also suffer a "disturbance" until it can make the necessary "work arounds," meaning that PALM will operate at sub-standard performance levels. Id. at ¶ 7. Additionally, the agency will have to process many erroneous document filings made by applicants who do not know of the preliminary injunction and attempt to comply with the Final Rules. Id. at ¶ 8. In total, the USPTO anticipates that the computer problems caused by an injunction will cost the agency at least $1.2 million and likely more. Id. at ¶ 9.

Plaintiffs attempt to trivialize the potential harm that a preliminary injunction would cause the USPTO by claiming that the USPTO "does not have much to gain from this rulemaking." Pl.

Mem. at 29. Nothing could be further from the truth. The USPTO has explained both in its Proposed and Final Rules that the growing number of continuing applications, as well as the increasing number and complexity of claims in patent applications, is crippling the Office's ability to examine newly-filed applications. Ex. 2 No. at 46718; Ex. 3. at 48, 49-50, 61-62. As the agency's own quality control standards show, USPTO examiners commit a far higher proportion of errors in examining applications with over twenty-five claims than in applications with fewer claims. See Ex. 1, A05059. Final Rule 75 is designed to assist them in examining such large applications and thereby reduce that discrepancy. See Ex. 2 at 46721. If the rule is delayed, however, the public will be harmed by the issuance of more large patents that include invalid claims.

Finally, the Final Rules are part of a larger group of initiatives to improve the examination process and the quality of issued patents. In addition to the Final Rules, the Office has proposed and/or implemented other new rules to address accelerated examination, information disclosure statements, and alternative claims.[14] These rulemakings, along with the Final Rules, are expected to work synergistically to begin healing a wounded system. The Office's efforts will be hampered, if not halted entirely, should a preliminary injunction issue. The balance of the hardships thus tilts decidedly in the USPTO's favor.

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[14] See, e.g., Changes to Practice for Petitions in Patent Applications to Make Special and for Accelerated Examination, 71 Fed. Reg. 36323 (June 26, 2006); Changes to Information Disclosure Requirements and Other Related Matters, 71 Fed. Reg. 38808 (July 10, 2006); Examination of Patent Applications That Include Claims Containing Alternative Language, 72 Fed. Reg. 44992 (Aug. 10, 2007).

III. PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS.

Because the balance of the hardship tilts strongly toward the USPTO, Plaintiffs must show "a probability (not mere possibility)" that they will ultimately prevail on the merits. Direx, 952 F.2d at 813 (quotation omitted). "[I]f there is doubt as to the probability of plaintiff's ultimate success on the merits the preliminary injunction must be denied." Id. (quotation marks omitted). Here, there is ample reason to doubt that Plaintiffs will prevail on the merits.

A. The USPTO Acted Within Its Statutory Authority In Promulgating the Final Rules.

Contrary to Plaintiffs' suggestion, the USPTO acted well within its statutory grant of rulemaking authority in enacting the Final Rules. See 35 U.S.C. § 2(b)(2). Most importantly, the USPTO acted pursuant to its broad power to "establish regulations, not inconsistent with law" to "govern the conduct of proceedings in the Office." Id. § 2(b)(2)(A); see Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006) ("Under 35 U.S.C. § 2(b)(2), the PTO has broad authority to govern the conduct of proceedings before it . . . ."); Stevens v. Tamai, 366 F.3d 1325, 1333 (Fed. Cir. 2004) ("By this grant of power [§ 2(b)(2)(A)] we understand Congress to have delegated plenary authority over PTO practice . . . to the Office.") (internal quotation marks omitted). As the Federal Circuit held in In re Bogese, 303 F.3d 1368 (Fed. Cir. 2002), the USPTO "has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Id. at 1368.

This is precisely what the USPTO has done. Final Rules 78 and 114 address when applicants are required to justify a further continuing application or request for continued examination by submitting a petition to the Office. Final Rules 75 and 265 concern when

applicants must make a further evidentiary submission in support of a large number of claims.

Plaintiffs rely on the Federal Circuit's decision in Merck & Co., Inc. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), to suggest that the USPTO acted in excess of its statutory authority under § 2(b)(2)(A) because Congress has not vested the USPTO with "substantive rulemaking power." Id. at 1550. Merck is readily distinguishable. There, the USPTO had not exercised rulemaking authority at all. Rather, it had issued a policy statement concerning term adjustments on issued patents. Its policy statement was not a regulation that "govern[ed] the conduct of proceedings in the Office," 35 U.S.C. § 2(b)(2)(A), and for this reason, the Federal Circuit considered the statement to be "substantive," Merck, 80 F.3d at 1550-51.[15]

Here, by contrast, the USPTO has enacted rules that clearly "govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b)(2)(A). The Final Rules prescribe when and how an applicant may present claims, evidence, and argument to the agency. They do not affect the truly substantive rights of the patent applicant, i.e., the right to have a patent issue if the applicant's invention comports with the substantive criteria of 35 U.S.C. §§ 101, 102, 103, and 112.

That the procedures created by the Final Rules might sometimes affect substantive outcomes does not take them outside the USPTO's rulemaking authority. Indeed, it is well-settled that the fact that a rule places a condition on whether an application will issue as a patent does not make the rule "substantive" and beyond the scope of the USPTO's rulemaking authority. As the Federal Circuit's predecessor court stated in In re Van Ornum, 686 F.2d 937 (CCPA 1982):

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[15] Eli Lilly & Co. v. Board of Regents of University of Washington, 334 F.3d 1264 (Fed. Cir. 2003), does not provide support for Plaintiffs' claim. The Federal Circuit's reference to Merck in that case was pure dicta, as Eli Lilly conceded the validity of the USPTO regulation at issue. See id. at 1269 n. 1.

> True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the content of the PTO rules is "substantive" in this respect. The regulation clearly relates to application processing within the PTO in a manner consistent with statutory and case law, which is its principal business.

Id. at 945 (holding that USPTO rule, which required a particular disclaimer from applicants seeking more than one patent on an invention, was valid despite its alleged conflict with statute and case law). Thus, the USPTO may, under § 2(b)(2)(A), set burdens of proof. See Stevens, 366 F.3d at 1333. The Office also may, by rule, set the threshold showing necessary for seeking reissue of a patent. See Dethmers Mfg. Co. v. Automatic Equip. Mfg. Co., 293 F.3d 1364 (Fed. Cir. 2002). Each of these rules, like those at issue here, governed application processing and were held to be within the USPTO's rulemaking authority.

Furthermore, § 2(b)(2)(A) is not the only relevant source of rulemaking authority. Under 35 U.S.C. § 2(b)(2)(C), the USPTO may establish regulations that "shall facilitate and expedite the processing of patent applications." Further, under 35 U.S.C. § 2(b)(2)(D), the Office may promulgate regulations to "govern the . . . conduct of agents, attorneys, or other persons representing applicants or other parties before the Office." In enacting rules aimed at improving the quality and efficiency of patent examinations by putting an end to dilatory conduct, the USPTO also acted well within these additional statutory grants of rulemaking authority.[16]

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[16] Plaintiffs cite to pending legislation as evidence that the USPTO does not have the power to promulgate the Final Rules. Pl. Mem. at 16-17. Yet "unenacted approvals, beliefs, and desires are not laws." Puerto Rico Dep't of Consumer Affairs v. ISLA Petroleum Corp., 485 U.S. 495, 501 (1988). Moreover, mere non-adoption of legislative bills is not probative of congressional intent, because "'several equally tenable inferences' may be drawn from such inaction, 'including the inference that the existing legislation already incorporated the offered change.'" Pension Benefit Guaranty Corp. v. LTV Corp., 496 U.S. 633, 650 (1990) (quoting United States v. Wise, 370 U.S. 405, 411, (1962)). To the extent the Court nevertheless

B. The Final Rules Are Consistent With the Patent Act and Are Reasonable.

Because the USPTO acted pursuant to its rulemaking authority, the Final Rules are entitled to Chevron deference as long as they do not conflict with express statutory language and are reasonable. See Chevron USA, Inc. v. NRDC, Inc., 467 U.S. 837 (1984); Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006) (granting the USPTO Chevron deference where it had enacted rules pursuant to § 2(b)(2)). Under Chevron, if Congress "has directly spoken to the precise question at issue" and its intent is clear, then "the court, as well as the agency, must give effect to [that] unambiguously expressed intent." Id. at 842-843. If, however, "the statute is silent or ambiguous with respect to the specific issue," the court must defer to the agency's rule as long as it is "based on a permissible construction of the statute." Id. at 843; see Lacavera, 441 F.3d at 1383 ("We must first determine whether the statute speaks to the issue of the challenge, and if the statute is silent or ambiguous, we must defer to the agency's reasonable interpretation.").[17] Each of the challenged rules is entitled to Chevron deference.

1. The Continuing Applications Rule (Final Rule 78)

Plaintiffs mistakenly contend that the USPTO's continuing application rule conflicts with 35 U.S.C. § 120. Section 120 merely provides a mechanism by which some later-filed

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considers the pending legislation, it should be noted that the House bill Plaintiffs rely on simply "clarifies the scope of power granted to the [USPTO] by paragraph (2) of section 2(b) of title 35." H.R. 1908, 110th Cong. § 14(b) (2007) (emphasis added). The House bill does not suggest that the USPTO previously lacked power to regulate in this area.

[17] Even if the USPTO had engaged in substantive rulemaking and thus received only Skidmore deference, as in Merck, the Final Rules still withstand judicial scrutiny. See Merck, 80 F.3d at 1550 (citing, inter alia, Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

applications may take the priority date of pending prior-filed applications.[18] The section says nothing about whether reasonable conditions may be placed upon the later filings. Section 2(b)(2)(A), by contrast, affirmatively gives the Director authority to govern the conduct of proceedings in the Office, § 2(b)(2)(C) calls for rules to facilitate and expedite patent proceedings, and § 2(b)(2)(D) affords the USPTO power to regulate conduct before the Office. See 35 U.S.C. § 2(b)(2). Because Section 120 is silent about conditions that may be imposed on additional filings, the USPTO may exercise its § 2(b)(2) rulemaking authority to promulgate reasonable regulations that prevent applicants from filing excessive applications directed to the same subject matter (thereby duplicating proceedings), and from delaying the presentation of claims to additional inventions through repeated continuations (thereby indefinitely prolonging proceedings). See Chevron, 467 U.S. at 842-43.

Indeed, the Federal Circuit has made clear in two recent cases that the USPTO may impose

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[18] Section 120 provides, in relevant part:

> 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, **if** filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120 (emphases added). Plaintiffs contend that the use of the word "shall" suggests that the USPTO has no choice but to allow unlimited continuing applications. Pl. Mem. at 17. Plaintiffs' selective quotation of the statute distorts its meaning. See id. (cutting off § 120 before the word "if"). When one reads the full sentence, it is clear that the word "shall" simply expresses that applicants will only benefit from the earlier application's filing date "if" they comply with the requirements of the statute.

reasonable limits on the continuing applications an applicant may file under § 120. See Bogese, 303 F.3d at 1367-68 (holding that § 120 does not preclude the USPTO from rejecting a continuing application on grounds of "prosecution laches"—i.e., on grounds that the applicant has delayed too long in filing the continuing application); Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 277 F.3d 1361, 1365-66 (Fed. Cir. 2002) (same).[19] In Bogese, the court held that "[l]ike other administrative agencies, the PTO may impose reasonable deadlines and requirements on parties that appear before it." 303 F.3d at 1368. Final Rule 78 is merely an effort by the USPTO to impose reasonable requirements on the filing of continuing applications.

The nearly forty-year old decision in In re Henriksen, 399 F.2d 253 (CCPA 1968), relied on by Plaintiffs, does not preclude the USPTO's reasonable regulations. In Henriksen, the Court of Customs and Patent Appeals condemned the Board for adopting an absolute limit on the number of continuing applications without the agency first engaging in notice and comment rulemaking. Here, of course, the USPTO engaged in notice and comment rulemaking, and there is no absolute limit on the number of continuing applications an applicant may file; he or she must simply meet the petition and showing requirement.[20] As the Federal Circuit explained in Bogese,

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[19] Plaintiffs cite a later decision, Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 422 F.3d 1378 (Fed. Cir. 2005) ("Symbol IV"), for the proposition that continuing applications must always be permitted except in the most extreme cases of prosecution laches. Pl. Mem. at 22. Yet even in Symbol IV, the Federal Circuit recognized that applicants may not file continuing applications that are "unduly successive or repetitive." Id. at 1385.

[20] Plaintiffs misconstrue the standard of the "petition and showing" requirement when they suggest that it is only met if an applicant could not have "physically" presented an amendment, evidence, or argument. Pl. Mem. at 19. As discussed in the Federal Register, although there are types of excuses that generally may not qualify for additional continuing applications, the USPTO will review petitions "on a case-by-case basis" to determine whether a satisfactory showing is made. See Ex. 2 at 46770-76.

the holding of Henriksen was "limited." Bogese, 303 F.3d at 1368 n. 6. "Nowhere does Henriksen suggest or imply that the PTO must allow dilatory tactics in the prosecution of applications or that PTO lacks inherent power to prohibit unreasonable delay in prosecution." Id.

Furthermore, Plaintiffs' reading of § 120 cannot be reconciled with other sections of the Patent Act. For example, 35 U.S.C. § 112 requires that a patent application specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Section 112 thus imposes a duty on applicants not to delay presenting claims to what they regard as their invention. Under 35 U.S.C. § 251, a patentee who mistakenly claims more or less than it has a right to claim in a patent, may surrender that patent and obtain reissue of the patent, correcting the error. But such a reissue patent may only expand the scope of the claims if applied for within two years of the original patent's issuance. Plaintiffs' theory would allow applicants to nullify § 251 by filing continuations solely to delay prosecution of all claims after a first patent has issued and entering broadened claims in some future continuation long after the two year limit.

Final Rule 78 represents a reasonable effort by the USPTO to ensure that undue delay in the prosecution of continuing applications does not continue to hamper the quality and efficiency of its patent examination. See generally Ex. 2 at 46716-18. Plaintiffs baldly assert that they have a right to deliberately delay presenting claims to the Office for examination and to prolong examination as long as suits their interests. See Pl. Mem. at 6. Section 120 does not authorize such purposeful delay.

Through Final Rule 78, the USPTO has simply said that there is some point in the patent prosecution process when strategic behavior that is impairing the agency's ability to function must

come to an end—when applicants must claim what they intend to claim. Section 120 does not preclude such reasonable measures, and § 2(b)(2) expressly authorizes them.

2. The Request for Continued Examinations Rule (Rule 114)

Plaintiffs similarly err in arguing that 35 U.S.C. § 132 authorizes applicants to submit unlimited and unconditional requests for continued examination. If Plaintiffs were correct, a USPTO examiner could never finally reject an application; an applicant could forever ask an examiner to reexamine his application rather than appeal the rejection to the Board. This cannot be and is not correct. See Ex. 2 at 46811.

Section 132(b) requires the USPTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." 35 U.S.C. § 132(b). The USPTO has done so. Final Rule 114 reasonably provides that an applicant who has received a final Office action may, as a matter of right, file one request for continued examination; after that, the applicant must request that the Office reexamine their application by filing a petition and making a showing as to why they could not have previously presented the argument, evidence, or amendment. See Ex. 2 at 46841, 37 C.F.R. § 1.114(f), (g). Nothing in Section 132(b) precludes this reasonable requirement.

3. The Claims Rule (Final Rules 75 and 265)

Plaintiffs further contend that 35 U.S.C. §§ 111 and 112 prevent the USPTO from requiring applicants who submit a burdensome number of claims to submit an examination support document to aid the examiner. Plaintiffs argue that "[t]hese sections do not remotely provide the Director with authority to limit the number of claims an applicant may file." Pl. Mem.

at 26. Plaintiffs' argument turns Chevron on its head and mischaracterizes the Final Rules.

As explained above, the USPTO derives its authority to issue Final Rules 75 and 265 from 35 U.S.C. § 2(b)(2). Under Chevron, the correct question is whether the statute unambiguously speaks to the precise question at issue. See Chevron 467 U.S. at 842-43. Sections 111 and 112 do not address whether the USPTO may require applicants who submit large numbers of claims to aid the USPTO in examining their application by submitting an examination support document. In the absence of language in §§ 111 and 112 prohibiting Final Rules 75 and 265, and in view of the USPTO's authority to issue regulations that "govern the conduct of proceedings in the Office" and "facilitate and expedite the processing of patent applications," 35 U.S.C. §§ 2(b)(2)(A), (C), the USPTO's reasonable attempt to assist examiners is entitled to the Court's deference.

C. The USPTO Did Not Act in an Arbitrary and Capricious Manner in Promulgating Rules that Aim to Improve the Quality and Efficiency of Patent Application Examination.

Judicial review of an agency's rulemaking under 5 U.S.C. § 706(2)(A) is guided by the highly deferential standard set forth in Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29 (1983). The scope of review under the arbitrary and capricious standard is narrow, as a court is not permitted to substitute its own judgment for that of the agency. See Id. at 43. If the agency's decision was "based on a consideration of the relevant factors," and there has not been a "clear error of judgment," the agency action must be upheld. Id. (internal quotation marks omitted).

Plaintiffs primarily complain that the USPTO did not adequately explain its

"administrative efficiency rationale" or "backlog rationale" for the Final Rules.[21] Pl. Mem. at 23. In fact, the USPTO has articulated its rationale quite clearly. See Ex. 2 at 46716-21. As explained in the Federal Register, by assuming that there are an unlimited number of continuations available, applicants have slipped into unfocused practices that impede the Office's ability to efficiently examine applications. Id. at 46720. By encouraging applicants to claim their inventions and present all evidence in their initial application, two continuation applications, and one request for continued examination, Final Rules 78 and 114 are expected to lead to more focused prosecution and to enable the Office to apply its patent examining resources now consumed by streams of continuation filings to the examination of new applications. See id. 46716-20. Allowing the Office to examine more new applications will clearly help reduce the backlog of unexamined applications.[22] See id. at 46717-19; id. at 46790 (noting that in 2006, the Office had a backlog of 701,147 applications). With regard to Final Rules 75 and 265, it is readily apparent why applications that contain a large number of claims would absorb an inordinate

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[21] Greater efficiency is only one of the goals of the Final Rules. The USPTO also expects to promote innovation by allowing the Office to examine more applications for new technologies and by giving the public notice of what technologies are and are not actually claimed in patent applications. See Ex. 2 at 46718. While Plaintiffs may not support these goals, other commentators, including Microsoft, IBM Corp., Apple Computers, Inc., Cisco Systems, Inc., and Intel, submitted comments supporting the Final Rules for these very reasons. See Ex. 1, A02972-75, A01357, A02715-16, A02718-20, A02360-63, A01387-92, A02749-61, A02242-51, A02139-42, A02252-53.

[22] Although as Plaintiffs note, only 2.7% of applications filed in 2006 would have required a petition and showing under the Final Rules, the 2.7% figure cited by Plaintiffs represents approximately 11,000 continuation applications and requests for continued examination, which is a year's work for 275 new patent examiners. See A05022; A05646. More significantly, Plaintiffs' argument fails to appreciate that the requirement to justify additional continuation applications, taken together with the other changes in the Final Rules, will induce applicants to file applications that are more precise and less riddled with errors that slow down examiners.

amount of patent examining resources, and why requiring the submission of an examination support document to accompany particularly large applications will assist the patent examiner in more efficiently examining those applications. See id. at 46721.

Plaintiffs further argue that the Final Rules are arbitrary and capricious because the USPTO ignored "less-drastic and less-damaging" alternatives and failed to consider "the dynamic effects" of the claims rules on patent applicants. Pl. Mem. at 23, 26. The USPTO squarely addressed these concerns in the Federal Register. See Ex. 2 at 46717-18. In part because of the very concerns Plaintiffs raise, the USPTO increased the number of continuing applications that could be filed without a petition and showing from one continuation or one continuation-in-part or one request for continued examination, as set forth in the Proposed Rules, to two continuation or continuation-in-part applications and one request for continued examination in the Final Rules. See id. at 47662. The USPTO also considered weaker alternatives but ultimately concluded that lesser measures, standing alone, would not adequately meet the Agency's dual goals. See Ex. 2 46816-23, 46824-26, 46833-34. Similarly, the USPTO considered the "dynamic effect" of the claims rules on patent applicants and took steps to prevent applicants from circumventing the rules.[23] See Ex. 2 at 46761, 46788, 46797-98. The USPTO's reasonable consideration of Plaintiffs' arguments, prior to promulgation of the Final Rules, satisfies the arbitrary and

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[23] The USPTO understands Plaintiffs' reference to "dynamic effects" to refer to ways in which applicants might alter their behavior to circumvent the 5/25 Rule. The USPTO enacted Final Rules 75(b)(4), 78(f)(1), and 78(f)(2) to combat such efforts, by preventing applicants from simply filing multiple applications on the same subject matter. See Ex. 2 at 46797-98, 37 C.F.R. §§ 1.75(b)(4), 1.78(f)(1), 1.78(f)(2) (setting forth rules (i) providing that co-pending applications that have patentably indistinct claims are treated as a single application for purposes of the 5/25 claim threshold; (ii) requiring applicants to disclose all applications that have at least one common inventor, were filed within two months, and have a common owner or assignee; and (iii) creating a rebuttable presumption that applications have indistinct claims if they are commonly-owned, have at least one inventor in common, and are filed on the same day).

capricious standard of review. See, e.g., Aaipharma Inc. v. Thompson, 296 F.3d 227, 242 (4th Cir. 2002) (holding that agency did not act arbitrarily and capriciously where it sufficiently considered comments); Maritel Inc. v. Collings, 422 F.Supp.2d 188, 201 (D.D.C. 2006) (same).

Lastly, Plaintiffs contend that the USPTO's own statistics fail to support the "backlog" rationale of the Final Rules. The nearly 10,000 page administrative record shows this contention to be false. See, e.g., Va. Agric. Growers Ass'n, Inc. v. Sec. of Labor, 774 F.2d 89, 93 (4th Cir. 1985) (rule was not arbitrary or capricious where administrative record explained agency's reasoning). The USPTO has modeled the impacts of the Final Rules (and other rule changes under consideration) on patent pendency. See, e.g., Ex.1, A05641-A05721. While the models show that the Final Rules, alone, are insufficient to reduce the growing backlog to a reasonable level within an acceptable period of time, the models do demonstrate that the changes in the Final Rules will have an appreciable impact on the backlog. See Ex. 1, A05645. Moreover, the Final Rules are not the only way the USPTO is seeking to improve the quality and efficiency of examinations; these rules are only one among many initiatives aimed at this goal. See Ex. 2 at 46819-20 & infra n. 14. Granting Plaintiffs' request for a preliminary injunction will disrupt this integrated scheme and will only increase the backlog of applications awaiting examination.

D. The Final Rules Governing Continuing Applications Are Not Retroactive.

Plaintiffs further err in contending that the Final Rules are retroactive. A regulation "does not operative retrospectively merely because it is applied in a case arising from conduct antedating the statute's enactment or upsets expectations based in prior law." Landgraf v. USI Film Prods., 511 U.S. 244, 269 (1994) (internal citation and quotation marks omitted). Nor is a regulation "'made retroactive merely because it draws upon antecedent facts for its operation.'" Id. at 270 n.

24 (quoting Cox v. Hart, 260 U.S. 427, 435 (1922)). Rather, a regulation is impermissibly retroactive only if it "would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed." Id. at 280 (emphases added).

Any effect the Final Rules might indirectly have on pending applications does not render them retroactive because the mere filing of an application does not create any "rights" or amount to "transactions already completed." See Cmty. TV, Inc. v. FCC, 216 F.3d 1133, 1143 (D.C. Cir. 2000) (holding that FCC was free to alter criteria for consideration of pending 'upgrade' applications because the mere filing of an application did not vest the applicant with a "legally cognizable expectation interest"); Chadmore Commc'n v. FCC, 113 F.3d 235, 240-41 (D.C. Cir. 1997) (holding that a new FCC rule could be applied to a pending application because the filing of an application did not complete a transaction and did not give rise to a vested right); Bergerco Canada v. U.S. Treas. Dep't, 129 F.3d 189, 193 (D.C. Cir. 1997) (holding that new Treasury rule could be applied to pending application for license to allow collection of debt payments without running afoul of Landgraf); see also GTE South, Inc. v. Morrison, 199 F.3d 733, 741 (4th Cir. 1999) (holding that regulation governing future business relations was not retroactive when applied to plaintiff who had no vested rights).

Citing no competent legal authority, Plaintiffs attempt to distinguish some of these cases by arguing that patent applications are "property." See Pl. Mem. at 25, To the contrary, it is well-established that patent applications do not give rise to property rights. See Marsh v. Nichols, Shepherd & Co., 128 U.S. 605, 612 (1888) ("Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce. Until then there is no power over its use, which is one of the elements of a right of property in anything capable of ownership."); Mullins

Mfg. Co. v. Booth, 125 F.2d 660, 664 (6th Cir. 1942); De Ferranti v. Lyndmark, 30 App. D.C. 417, at *5 (1908); see also Brenner v. Ebbert, 398 F.2d 762, 764-65 (D.C. Cir. 1968).[24] The cited cases are thus directly on point and preclude Plaintiffs' claim of retroactivity.

The Final Rules are not retroactive for another reason: They are procedural rules. As the Supreme Court explained in Landgraf, "[c]hanges in procedural rules may often be applied in suits arising before their enactment without raising concerns about retroactivity." 511 U.S. at 275; see also Combs v. Comm'r of Soc. Sec., 459 F.3d 640, 647 (6th Cir. 2006) ("[C]hanges to procedural rules generally do not have retroactive effect because procedural rules regulate secondary as opposed to primary conduct."). Final Rules 78 and 114 merely add an additional procedural requirement: the requirement of filing a petition and making a showing if the applicant wants to file a third continuation application or a second request for continued examination. Final Rule 75 does not place a limit on the number of claims an applicant may file, but simply requires the applicant to submit an extra document to assist the examiner in considering the excess claims.

[24] In their Verified Amended Complaint, Plaintiffs cite a Board of Tax Appeals case from 1933 for the proposition that patent applications are property. See Winchester v. Comm'r., 27 B.T.A. 783, 1933 WL 231, at 3 (Bd.Tax. App. 1933). It goes without saying that such a case has no precedential value in this Court and is plainly outweighed by the precedent cited above. In any event, the Board of Tax Appeals in Winchester was simply deciding whether, as a matter of statutory interpretation, patent applications could be considered property under the Revenue Act. See id. (relying on Comm'r v. Stephens-Adamson Mfg. Co., 51 F.2d 681 (7th Cir. 1931)). Plaintiffs also cite Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002-04 (1984), but insofar as patent applications must ordinarily be published eighteen months after their priority date, 35 U.S.C. § 122(b)(1); 37 C.F.R. § 1.211 (2006), it is clear that such applications do not constitute "trade secrets" that give rise to a vested property right. See Ruckleshaus, 467 U.S. at 1002 ("If an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished."); see also Memorandum in Support of Motion of Amicus Curaie American Intellectual Property Association for Leave to File Its Brief in Support of the "GSK" Plaintiffs' Motion for a [TRO] and Preliminary Injunction, Dkt. No. 30, p. 2 ("As a general rule, once a patent application is published trade secrecy is lost and the application's owner must rely exclusively on the issuance of patents for protection.").

These rules do not affect the substantive eligibility requirements for obtaining a patent, which are contained in 35 U.S.C. §§ 101, 102, and 103. See Combs, 459 F.3d at 647 (holding that where, after the plaintiff filed suit, Social Security Administration promulgated a new rule changing the presumption of whether obesity was a disability, the court could apply the new rule to the plaintiff's case because the "substantive requirements for disability eligibility have not changed, only the way in which the agency goes about determining whether they are present"); see also Van Ornum, 686 F.2d at 945. For this reason, too, therefore, the Final Rules are not retroactive.

E. Plaintiffs' Vagueness Challenge Fails Because There is No Due Process Interest in Patent Applications or Procedures, and in Any Event, the Examination Support Document Requirement Is Clear.

Plaintiffs further contend that the preexamination search requirement of Final Rule 265 is so "incomprehensibly vague" that it violates the due process clause of the Constitution. Pl. Mem. at 27 (complaining that "neither this rule nor the comments" expressly define the scope of a preexamination search that would comply with the regulation). Plaintiffs' vagueness challenge fails initially because Plaintiffs have no constitutionally-protected interest in either their patent applications, see Marsh, 128 U.S. at 612, or the procedures by which the USPTO examines their patent applications, see Olim v. Wakinekona, 461 U.S. 238, 250 (1983).[25] Plaintiffs' lack of such a constitutionally-protected interest forecloses its vagueness challenge. See Willis v. Town of Marshall, 426 F.3d 251, 261 (4th Cir. 2005) (noting that the "vagueness doctrine is rooted in due process principles" and rejecting such a challenge because the plaintiff lacked protected interests).

Plaintiffs' vagueness challenge also fails because it is clear how applicants are supposed to comply with the preexamination search requirement. Courts have long recognized that "specific

[25] United States v. Lanier, 520 U.S. 259, 266 (1997), which Plaintiffs rely upon, see Pl. Mem. at 26-27, is thus inapposite, as Plaintiffs are not similarly situated to a criminal defendant who has a liberty interest that may be jeopardized by a vague criminal statute.

regulations cannot begin to cover all of the infinite variety of . . . conditions which [individuals] must face," and that "[b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct which should be regulated to escape regulation." Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Rev. Comm'n., 108 F.3d 358, 362 (D.C. Cir. 1997) (citing Ray Evers Welding Co. v. OSHRC, 625 F.2d 726, 730 (6th Cir. 1980)); see also Grayned v. City of Rockford, 408 U.S. 104, 110 (1972) (recognizing that regulations need not be drawn with "mathematical certainty" or "meticulous specificity"). Accordingly, courts simply require a regulation to be specific enough that a "reasonably prudent person," familiar with the circumstances motivating the regulation and the regulation's goal, would have "fair warning" of what is required or prohibited. Freeman, 108 F.3d at 362; see also Boyce Motor Lines, Inc. v. United States, 342 U.S. 337, 340 (1952).

The USPTO's regulations clearly put prospective applicants on notice of what constitutes a sufficient preexamination search. In the final Federal Register notice, for example, the USPTO specifically addressed the appropriate scope of the required preexamination search. See, e.g., Ex. 2 at 46800-01; see also Ex. 4, Faile Decl. at ¶ 7. The USPTO explained that the "standard for the preexamination search that is required [under the Final Rules] is the same standard that the [USPTO] uses to examine patent applications, which is set forth in MPEP §§ 904-904.03.[26] Ex. 2 at 46800. The USPTO further explained that if an "applicant follows the search guidelines set forth in the MPEP, then the preexamination search should be sufficient." Id. (emphasis added). Furthermore, Plaintiffs concede (as they must), see Pl. Mem. at 27, that USPTO has published official guidance providing further explanation regarding the scope of the preexamination search

[26] The MPEP is publically available on the USPTO's web site and contains extensive information explaining the search of prior art. See MPEP ch. 900

requirement. See e.g., Ex. 4, Faile Decl. at Ex. A "Guidelines for Examination Support Document ("ESD") under 37 CFR 1.265,"[27]; id. at Ex. B "Frequently Asked Questions; MPEP Chapter 900. This guidance, which is publically available on the USPTO website, provides specific examples of searches that comply with the Final Rules' requirements. The declaration of Mr. Faile further sets out numerous other steps the USPTO has taken to ensure that applicants understand how to comply with Final Rule 265. See Ex. 4, Faile Decl. at ¶¶ 11-16.

In the end, although Final Rule 265 itself does not address every imaginable circumstance that may confront a patent applicant conducting a search – and due process does not require as such – when combined with the final Federal Register notice, the MPEP, and the USPTO's extensive public guidance, the rule clearly passes constitutional muster. See, e.g., Grayned, 408 U.S. at 110 (noting that due process does not require regulations to be drawn with precision, but rather they may embody "flexibility and reasonable breadth").

IV. THE PUBLIC WILL BE HARMED IF THE COURT ISSUES A PRELIMINARY INJUNCTION.

The public has a strong interest in the Final Rules going into effect. As Plaintiffs concede, the public's interest lies in "promoting innovation." Pl. Mem. at 29. The Final Rules promote

[27] In the final Federal Register notice, the USPTO explicitly informed the public that such official guidance would be forthcoming. See Ex. 2 at 46716. Indeed, in further explaining the requirements for an ESD, the final Federal Register notice references the requirements of an "accelerated examination support document" ("AESD"), a document similar to an ESD but which contains more stringent requirements. Therefore, as the Notice indicates, the USPTO's guidelines concerning the AESD may be helpful to applicants who are preparing an ESD under § 1.265. See Ex. 2 at 46716; see also Ex. 4, Faile Decl. at ¶¶ 17-21. The Notice explains that the guidelines for the AESD, search templates, and samples of a preexamination search document and an examination support document can be found on the USPTO's Internet Web site at http://www.uspto.gov/web/ patents/accelerated/. Id. Importantly, the Notice expressly states that the USPTO "will provide similar guidelines for examination support document under § 1.265 and will post such guidelines on the Office's Internet Web site." Ex. 2 at 46716.

innovation by ensuring an agency that runs efficiently and allows new inventions to be reviewed in a timely manner. Moreover, the public includes not just industry giants like Plaintiffs, but also entrepreneurs who are considering starting and expanding businesses but who face difficulty determining what patents will issue to others under the current system. See id. at 46718 (explaining that "when the continued examination process fails to reach a final resolution . . . the public is left with an uncertainty as to what the set of patents resulting from the initial application will cover"). The Final Rules will further promote innovation by enabling this segment of the public to know what technology is and is not available for their use. See id.; see also Ex. 1, A01275-01285, A02668-02677 (comments of U.S. Department of Justice Antitrust Division and U.S. Federal Trade Commission, discussing how the Final Rules will promote innovation). By contrast, intentionally delaying the presentation of claims and endlessly injecting continuation applications into the system to recycle or rework material that has already been examined does not promote innovation. See generally Ex. 2 at 46716-20.

Finally, during the seventy-one days between the publication of the Final Rules and the date of argument on the Plaintiffs' preliminary injunction motion, other patent applicants have been diligently preparing to comply with the new rules. A preliminary injunction would undermine their efforts. Moreover, applicants who may not be aware of the preliminary injunction may begin to make filings based on the Final Rules. Such applicants will find themselves caught between regulatory regimes, uncertain about how to proceed with prosecution.

In sum, this fourth prong of the preliminary injunction test, like each of the three prongs preceding it, weighs against this Court enjoining the Final Rules on the eve of implementation.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' motion for a temporary restraining order and preliminary injunction and allow the Final Rules to take effect on November 1, 2007, as planned.

Respectfully submitted,

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