From: Ron Henderson [ronald.henderson@BTLaw.com]
Sent: Wednesday, January 16, 2008 4:41 PM
To: FN-USTR-FR0606
Subject: Special 301 Review

As stated in the very first sentence of the Request for Written Submissions from the public in Federal Register/Vol. 73, No. 11/Wednesday, January 16, 2008/Notices in the center column (near the bottom) of page 2958, "Section 182 of the Trade Act (Trade Act) (19 U.S.C. 2242) requires the United States Trade Representative (USTR) to identify countries that deny adequate and effective protection of intellectual property rights . . . to U.S. person who rely on intellectual property protection."

The United States Patent & Tradmark Office is attempting to implement new rules in Title 37 of the Code of Federal Regulations that limit the number of continuing patent applications that patent Applicants, including US persons, can file and that place extremely onerous burdens on patent Applicants, including US persons, who wish to file more than 5 independent claims and/or 25 total claims in a single patent application (or in a combination of applications that are filed 2 months before or 2 months after the application, that have a common inventor, and that the USPTO deems "substantially overlap" with regard to the subject matter of the application . . . with the test for substantial overlap being that the other application has a disclosure which supports one claim of the present application). These rules were published to the public and discussed by the USPTO in Federal Register/Vol. 72, No. 161/Tuesday, August 21, 2007/Rules and Regulations at pages 46716 through 46843.
Presently, the USPTO has been preliminarily enjoined from implementing those rules by the U.S. Dist. Ct. for the Eastern District of Virginia (see the judges Order of 10/31/07 in the case Triantafyllos Tafas v. Jon W. Dudas, et al. consolidated with Smithkline Beecham Corp. v. Jon W. Dudas, et al. attached to this e-mail as a PDF).

If the USPTO gets its proposed continuation practice and claim practice rules implemented, either by winning the present lawsuit or by doing an end run through Congress with regard to getting the rules implemented, then I would suggest that the United States would be a country that denies adequate and effective protection of intellectual property rights. The rules proposed by the USPTO effectively limit the ability of Applicants, including U.S. persons, to fully claim their inventions and therefore, deny adequate and effective protection of intellectual property rights.

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

Alexandria Division

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

CONSOLIDATED WITH

	)	
SMITHKLINE BEECHAM	)	
CORPORATION, et al.	)	
	)	
Plaintiffs	)	
	)	
v.	)	1:07cv1008 (JCC)
	)	
JON W. DUDAS, et al.,	)	
	)	
Defendants.	)	

M E M O R A N D U M O P I N I O N

This matter is before the Court on: (1) Plaintiffs Smithkline Beecham Corporation and Glaxo Group Limited's ("GSK") Motion for a Temporary Restraining Order ("TRO") and Preliminary Injunction; (2) Defendants Jon W. Dudas and United States Patent and Trademark Office's ("PTO") Motion to Strike Exhibit E of the Memorandum in Support of GSK's Motion; (3) the Motion of *Amicus Curiae* American Intellectual Property Law Association ("AIPLA")

for Leave fo File its Brief in Support of GSK's Motion; (4) HEXAS, LLC ("Hexas"), The Roskamp Institute, and Tikvah Therapeutics, Inc.'s ("Tikvah") Joint Motion in Support of Motion for Leave to File *Amici Curiae* Brief in Support of GSK's Motion; and (5) the Motion of *Amicus Curiae* Elan Pharmaceutical Corp. for Leave to File its Brief in Support of GSK's Motion. For the reasons stated below, the Court will grant GSK's motion, deny the PTO's motion, and grant the motions for leave to file as amici.

I. Background

GSK is the second largest pharmaceutical company in the world and is responsible for developing and marketing drugs that treat numerous ailments, including cancer, cardiovascular disease, respiratory diseases, HIV, and depression. The patent system encourages companies like GSK to engage in the research and development of new drugs by providing them with the legal protection that enables them to recover the significant costs that accompany development and regulatory approval of new drugs. This case deals with potential changes to this system brought on by the PTO's modification of several long-established rules.

Under both the old and new rules, to obtain patent protection an inventor first files a patent application with the PTO. The first application filed for a given invention is a "parent" or "initial" application. A parent application contains two primary parts: a "specification," which describes the

invention and how to make and use it, and one or more "claims," which identify the scope of the legal protection that the invention should receive, and come in either "independent" or "dependent" forms. Once the application is filed, a patent examiner determines whether the claimed invention meets the statutory requirements found in Title 35 of the United State Code. If it is rejected, the examiner will issue an "Office Action" that contains the grounds for rejection. An applicant may then amend the claims, argue against the rejection, or present evidence to show why the invention is patentable. The patent examiner must respond by either allowing or rejecting the claim.

Upon receiving a final rejection, an applicant has four choices: (1) appeal to the Board of Patent Appeals and Interferences and from there to the Federal Circuit; (2) file a "request for continued examination" ("RCE") of the application; (3) file a "continuation" or "continuation-in-part" application; or (4) file an after final "amendment." A continuation application uses the same specification as the pending parent application and enjoys the benefit of the filing date of the parent application (the "priority date").

In situations where an applicant claims more than one independent invention in the initial application, the examiner may impose a "restriction requirement" that forces an applicant

to separate their multiple independent inventions into "divisional" applications that claim a single invention. The applicant must then choose one of the inventions to prosecute in their initial application, and can prosecute the remaining inventions in their divisional applications, which claim the priority date of the parent application.

On January 3, 2006, the PTO proposed changes to its rules that would limit the number of continuing applications, RCEs, and claims that an applicant could make. The PTO justified the proposed changes on the ground that the growing number of continuing applications and increasing number and complexity of claims in applications had crippled the PTO's ability to examine newly-filed applications. After a four month public comment period where the PTO received more than 500 written comments, many of which expressed disapproval with the proposed rules, on August 21, 2007, the PTO published the Final Rules, titled "Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications." 72 Fed. Reg. 46716-46843 (Aug. 21, 2007)(to be codified at 37 C.F.R. pt. 1). The Final Rules are set to take effect on November 1, 2007.

Under the old system, an applicant could file an unlimited number of continuing applications, RCEs, and claims. The Final Rules modify that system in the several ways. First,

Final Rules 78 and 114 allow an applicant to file two continuation or continuation-in-part applications, plus a single RCE, after an initial application as a matter of right. If the applicant wants to engage in further prosecution, a third continuation or continuation-in-part application or a second RCE can be filed with a "petition and showing" that explains why the amendment, argument, or evidence could not have been presented in one of the previously-filed applications. These Final Rules apply to all initial and continuing applications filed on or after November 1, 2007. In addition, under Final Rule 142, if the applicant submits an application with multiple independent inventions, with the examiner's permission a divisional application may be filed for each invention, and each divisional application will be treated as an initial application.

Second, Final Rule 75 permits an applicant to present a total of five independent claims and twenty-five total claims without providing any further information about those claims. An applicant who wants to exceed either of these limitations must provide an "examination support document" ("ESD") containing information about the claims that may assist the examiner in determining the patentability of the claimed invention. The requirements of an ESD are set out in Final Rule 265. These Final Rules apply 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.

Under the old system, GSK would traditionally prosecute patents in the following manner. When GSK discovered a potential class of new drug products (a "genus"), it would typically file an initial application containing a broad disclosure that includes numerous structurally-related compounds (a "species"). This broad disclosure would include a number of different inventions and disclose more than it claims. Because GSK does not know until after extensive research is performed which member of the genus will be brought to market, it would file an initial application with the understanding that it will prosecute narrower or additional patent claims in subsequent continuing applications.[1] These continuing applications can claim the priority date of the parent application; consequently, publications and public information generated between the priority date and the date of the later-filed applications cannot be used against patentability.

GSK currently has roughly 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. GSK also has several pending applications that have not

[1] "Continuation," "continuation-in-part," and "divisional" applications are all commonly referred to as "continuing applications."

yet received an Office Action on the merits and contain enough claims to trigger an ESD.

On October 9, 2007, GSK filed a Complaint against the PTO seeking a preliminary injunction staying the implementation of the Final Rules until the resolution of the lawsuit, a permanent injunction against the implementation of the Final Rules, a declaratory judgment that the Final Rules are contrary to law, and a request that the Final Rules be vacated. Two days later, GSK filed an Amended Complaint against the PTO seeking the same relief. On October 15, 2007, GSK moved for a TRO and preliminary injunction enjoining the implementation of the Final Rules. On October 19, the PTO moved to strike the declaration of Harry F. Manbeck, Jr., Exhibit E of the Memorandum in Support of GSK's Motion. In addition, numerous entities have filed motions for leave to file *amicus curiae* briefs, including: (1) AIPLA on October 25; (2) HEXAS, The Roskamp Institute, and Tikvah, jointly, on October 26; and (3) Elan Pharmaceuticals on October 29. These motions are currently before the Court.

II. Standard of Review

The Federal Circuit has generally treated the grant or denial of a preliminary injunction as a procedural matter and thus has applied the procedural law of the regional circuit in which the case was brought. *See Texas Instruments, Inc. v. Tessera, Inc.*, 231 F.3d 1325, 1328 (Fed. Cir. 2000); *Mikohn v.*

Gaming Corp. v. Acres Gaming, Inc., 165 F.3d 891, 894 (Fed. Cir. 1998). However, where "the issue pertains to or is unique to patent law," the Federal Circuit has applied its own law to both substantive and procedural issues "intimately involved in the substance of enforcement of the patent right." *Amana Refrigeration, Inc., v. Quadlux, Inc.*, 172 F.3d 852, 856 (Fed. Cir. 1999)(citations omitted); *see also Mikohn*, 165 F.3d at 894 (stating that the Federal Circuit has given "dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues"). To the extent that GSK's Motion deals with the propriety of the Final Rules under the patent laws, the Court will apply the law of the Federal Circuit with respect to the issuance of a preliminary injunction. *See Mylan Pharms., Inc. v. Thompson*, 268 F.2d 1323, 1329 n.1 (Fed. Cir. 2001)(finding that Federal Circuit law applied to a preliminary injunction motion involving the enforcement of patent rights); *Texas Instruments*, 231 F.3d at 1328 (finding that Federal Circuit law applied to a preliminary injunction motion involving substantive issues in an area of law within the unique jurisdiction of the Federal Circuit).

The four factors relevant to the Court's decision to grant or deny a preliminary injunction are: "(1) the likelihood of [the plaintiff's] success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships

between the parties; and (4) the public interest." *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007) (citations omitted).[2] "These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested." *Amazon.com, Inc. v. Barnesandnodble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)(citations omitted).

The Court has broad discretion in deciding whether to allow a non-party to participate as an *amicus curiae*. *See, e.g., Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982); *Waste Mgmt., Inc. v. City of York*, 162 F.R.D. 34, 36 (M.D. Pa. 1995). Such non-party participants have "been allowed at the trial level where they provide helpful analysis of the law, they have a special interest in the subject matter of the suit, or existing counsel is in need of assistance." *Bryant v. Better Business Bureau*, 923 F. Supp. 720, 727 (D. Md. 1996)(internal citations omitted); *see also Northern Sec. Co. v. United States*, 191 U.S. 555, 556 (1903). However, "[a] motion for leave to file an amicus curiae brief . . . should not be granted unless the court 'deems the proffered information timely and useful.'" *Bryant,*

[2] Alternately, under Fourth Circuit law the standard for preliminary injunctions is substantially similar. *See Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189, 193 (4th Cir. 1977).

923 F. Supp. at 727-28 (citing *Yip v. Pagano*, 606 F. Supp. 1566, 1568 (D.N.J. 1985)).

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, amended effective December 1, 2000 to reflect the Supreme Court's rulings in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). It provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. A district court's decision with respect to the admissibility of expert scientific testimony "is always a flexible one, and the court's conclusions necessarily amount to an exercise of broad discretion guided by the overarching criteria of relevance and reliability." *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999); *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 200 (4th Cir. 2001)(noting the Supreme Court's statement in *Kumho Tire* that trial judges "must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony

is reliable") (quoting *Kumho Tire*, 526 U.S. at 152); *United States v. Barnette*, 211 F.3d 803, 816 (4th Cir. 2000)(noting the Fourth Circuit's consistent practice of giving "great deference" to a trial Court's *Daubert* ruling).

III. Analysis

GSK seeks a TRO and a preliminary injunction preventing the PTO from implementing the Final Rules, the PTO moves to strike the declaration of Harry F. Manbeck, Jr., Exhibit E of the Memorandum in Support of GSK's Motion, and numerous entities have filed three separate motions for leave to file *amicus curiae* briefs. The Court will address the *amicus* issue and the PTO's motion first before turning to GSK's motion.

A. Motions for Leave to File *Amicus Curiae* Briefs

Plaintiffs Tafas and GSK have consented to the filing of the *amicus curiae* motions of Elan, Hexas, the Roskamp Institute, Tikvah, and AIPLA. The PTO opposes all of the filings as untimely. However, the cases the PTO cites in support of their claim that these filings are untimely involve situations in which the motions to file as amicus were made months after the cases were filed and the courts had begun holding hearings. *See, e.g., Centeno-Bernuy v. Perry*, 302 F. Supp. 2d 128, 131 (W.D.N.Y. 2003) (finding that "the motion is untimely as the hearing has been completed and the preliminary injunction motion has been submitted for decision"); *O Centro Espirita Beneficente Uniao do*

Vegetal v. Ashcroft, 282 F. Supp. 2d 1271, 1274 (D.N.M. 2002) (denying a motion to enter as an amicus after parties had "prepared numerous briefs . . . over a period of more than a year, . . . [and] presented evidence and arguments at a lengthy hearing"). Rather than frequently turning down amicus briefs on timeliness grounds, courts have accepted them as timely even when filed "on the eve of summary judgment motions." *Community Ass'n for Restoration of the Env't v. Deruyter Bros. Dairy*, 54 F. Supp. 2d 974, 975-976 (E.D. Wash. 1999). This case was filed on October 9, 2007, and the parties seeking to be heard as *amici curiae* filed their motions before the first hearing. Because these amicus briefs were filed a relatively short time after the case began, the Court will find that they are sufficiently timely.

The PTO also objects to AIPLA's proposed amicus brief on the grounds that it improperly contains new arguments not contained within GSK's brief. The Court agrees that it may not consider legal issues or arguments not raised by the parties. *See, e.g. Cellnet Communs. v. FCC*, 149 F.3d 429, 443 (6th Cir. 1998)(holding that "[t]o the extent that the amicus raises issues or make arguments that exceed those properly raised by the parties, [the Court] may not consider such issues"). However, the mere fact that a non-party seeks to put forth an opinion in the case does not disqualify it as an amicus. Although "[a]n

amicus . . . is not a party to the litigation and participates only to assist the court[, n]evertheless, 'by the nature of things an amicus is not normally impartial' . . . and 'there is no rule . . . that amici must be totally disinterested.'" *Waste Mgmt., Inc. v. City of York*, 162 F.R.D. 34, 36 (D. Pa. 1995) (quoting *United States v. Gotti*, 755 F. Supp. 1157, 1158 (E.D.N.Y. 1991) and *Concerned Area Residents for the Environment v. Southview Farm*, 834 F. Supp. 1410, 1413 (W.D.N.Y. 1993)). Therefore, the Court will grant each of the three motions for leave to file an *amicus curiae* brief, but will not consider any legal issues or arguments therein that were not raised by the parties themselves.

B. Admissibility of the Manbeck Declaration

Defendants move to strike the declaration of Harry F. Manbeck, Jr., Exhibit E of the Memorandum in Support of GSK's Motion, on grounds that it is not allowable under the Federal Rules of Evidence, it impermissibly augments the administrative record, and it is in violation of the local rules. The Court will take each concern in turn.

1) Expert Testimony

The PTO argues that the Manbeck Declaration is inappropriate in that it is primarily a rendering of legal conclusions and is therefore not relevant, helpful, or needed by the Court in its determination of whether a preliminary

injunction is appropriate in this case. The Federal Circuit, which regularly hears questions of patent law, "has on numerous occasions noted the impropriety of patent lawyers testifying as expert witnesses and giving their opinion regarding the proper interpretation of a claim as a matter of law, the ultimate issue for the court to decide." *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997). However, patent lawyers frequently testify as expert witnesses as to matters of PTO practice and procedure and to explain the complexities of patent prosecution, and a "judge can even advert to the testimony of patent law experts -- that is, patent lawyers -- for advice on the interpretation of claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 991 (Fed. Cir. 1995)(emphasizing the importance of expert witnesses in the field of patents to "reveal how others use and understand technical terms that may appear ambiguous or opaque to the judge, who rarely has the knowledge of those skilled in the field of the patent"). Insofar as the Manbeck Declaration renders legal conclusions, the Court agrees that it is inappropriate. However, the Court also recognizes its own limited knowledge of the intricacies of patent regulations and appreciates the need for experts in this matter.

In a situation similar to this one, a trial court declined to strike a patent lawyer's expert report upon

allegations that it "consist[ed] solely of legal conclusions disguised as expert testimony." *Chamberlain Group, Inc. v. Interlogix, Inc.*, 2002 WL 653893, *1 (N.D.Ill.,2002). The Court reasoned that excluding the entire report would be "an extraordinary measure" and chastised the moving party for "fail[ing] to identify specific portions of [the expert's] report that it contends should be stricken." *Id.* The report at issue "provide[d] an explanation of the prosecution history of the patents at issue, and the operation of the Patent and Trademark Office," thus helping the Court to understand the patent issues in the case. *Id.*

Similarly, the PTO does not delineate particular portions of Manbeck's expert testimony that they wish to strike, claiming that the entire report is tainted. The Court recognizes that the Manbeck Declaration contains some impermissible legal arguments, but agrees with the *Chamberlain* Court that striking the entire report would be extraordinary, particularly given Manbeck's obvious qualifications in the field and clear ability to explain the complexities of patent regulation and the background of this matter. Therefore, the Court will accept the Declaration as the statement of an expert witness, but will not take into account any impermissible legal argument contained therein.

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2) Augmentation of administrative record

The PTO alleges that the Manbeck Declaration "impermissibly introduces into the administrative record . . . material that was not before the USPTO when it enacted the Final Rules." Mem. in Supp. of Defs.' Mot. to Strike Ex. E at 6. Generally, "judicial review of agency action pursuant to the APA is confined to the agency's administrative record." *American Canoe Ass'n v. United States EPA*, 46 F. Supp. 2d 473, 475 (E.D. Va. 1999)(citing *Camp v. Pitts*, 411 U.S. 138, 142, (1973)). The Manbeck Declaration does contain analysis that goes beyond mere explanation of the administrative record. However, "[e]ven in APA record review cases, circumstances may justify expanding the record or permitting discovery," including "such a failure in the record to explain administrative action as to frustrate judicial review, the agency's reliance on materials or documents not included in the administrative record, or the need to supplement the record to explain or clarify technical terms or other difficult subject matter included in the record." *Id.* at 477 (internal citations omitted); *see also Public Power Council v. Johnson*, 674 F.2d 791, 793-94 (9th Cir. 1982) (holding that "there may be circumstances to justify expanding the record or permitting discovery," including "ascertaining whether the agency considered all the relevant factors or fully explicated its course of conduct or grounds for decision," situations "when it

appears the agency has relied on documents or materials not included in the record," and other circumstances as "necessary to permit explanation or clarification of technical terms or subject matter involved in the agency action under review" as "background information"). Not only are there situations in which external information can be helpful to the Court, but the D.C. Circuit has pointed out that it can be reversible error for a district court to avoid going outside the administrative record in some situations. *Esch v. Yeutter*, 876 F.2d 976, 992 (D.C. Cir. 1989). It recognized that extra-record evidence can be important in scenarios "when a case is so complex that a court needs more evidence to enable it to understand the issues clearly" and "in cases where relief is at issue, especially at the preliminary injunction stage," among others. *Id.* at 991.

In this consideration of a preliminary injunction, given that the subject matter is difficult and there are a number of terms used uniquely in the patent context, the Court finds that some explanatory material is appropriate. The Manbeck Declaration relies on statutes, court cases, Congressional documents, and the PTO's own publications, not on rare sources or information that the PTO was unaware of. In fact, the Court would find it extremely unusual if the PTO had not taken into consideration statutes, patent case law, and declarations of Congress in its promulgation of the Final Rules, even if they are

explicitly referenced in the administrative record. Therefore, the Court will find that the external material relied upon in the Declaration is appropriate for the purpose of providing explanatory and background information for the Court.

3) Compliance with the Local Rules

The PTO's third argument is that the Manbeck Declaration is an extension of GSK's brief and an attempt to circumvent the Local Rules page requirement, rather than a truly separate exhibit. Local Rule 7(F)(3). It is not inappropriate for a party to include exhibits or declarations in addition to its briefs, and the PTO itself included exhibits that explain the implications of the Final Rules. *See, e.g.*, Decl. of Andrew Faile, Ex. 4 to Defs.' Opp. to Pls.' Mot. for a TRO and Prelim. Inj. As discussed above, GSK includes the Manbeck Declaration in order to assist the Court in resolving a case that involves complex patent issues. Although the Declaration includes some legal conclusions, there are no significant arguments contained in the Declaration that are not also found in the brief itself. The Manbeck Declaration is an exhibit, not a continuation of GSK's brief, and in no way violates the Local Rules of the Court.

For the foregoing reasons, the Court will deny the PTO's Motion to Strike the Manbeck Declaration, but will not consider those parts of the Exhibit which contain impermissible legal arguments.

C. GSK's Motion for a TRO and Preliminary Injunction

In carefully weighing the factors of the Federal Circuit's balancing test, for the reasons stated below, the Court will grant GSK's Motion for a Preliminary Injunction.

1) Likelihood of Success on the Merits

GSK first argues that they will succeed on the merits because the PTO lacks the authority to promulgate substantive rules and therefore the PTO's interpretation of the Patent Act is not owed *Chevron* deference. *See Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990); *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984). More specifically, GSK argues that, because Congress did not grant the PTO the authority to construe provisions of the Patent Act except in certain, limited instances, *Chevron* deference to the PTO's interpretations of law in this area is inappropriate. Instead, under *Adams Fruit*, the PTO is entitled no deference. *Adams Fruit*, 494 U.S. at 649-50.

Section 2(b)(2) of Title 35 empowers the PTO to "establish regulations, not inconsistent with law," for several enumerated purposes, the most relevant of which include regulations to "govern the conduct of proceedings in the Office," 35 U.S.C. §§ 2(b)(2)(A), and to "facilitate and expedite the processing of patent applications." 35 U.S.C. § 2(b)(2)(C). The PTO thus has the power to "set reasonable deadlines and requirements for the prosecution of applications." *In re*

Borgese, 303 F.3d 1362, 1368 (Fed. Cir. 2002). Section 2(b)(2) does not, however, vest the PTO with any general substantive rulemaking power. *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). This conclusion is further evidenced by the fact that, since 2005, Congress has debated and considered whether it should grant the PTO substantive rulemaking authority. *See* Manbeck Decl., Ex. E to Mem. in Support of Pls.' Mot. for a TRO and Prelim. Inj. at ¶ 11; H.R. 1908, 110th Cong., § 14(a)(2007).

The PTO contends that the Final Rules fall within the scope of their Section 2(b)(2) authority because they "govern the conduct of proceedings in the Office" and "do not affect the truly substantive rights of the patent applicant." Defs.' Opp'n to Pls.' Mot. at 22. Specifically, the PTO asserts that the Final Rules do not affect the substantive eligibility requirements for obtaining a patent. *Id.*; *see also* 35 U.S.C. §§ 101, 102, and 103. They further assert that even if the procedures created by the Final Rules sometimes affect substantive outcomes, that does not place the Final Rules outside of the PTO's rulemaking authority. Defs.' Opp'n to Pls.' Mot. at 22.

In *In re Van Ornum*, cited by the PTO, the Federal Circuit's predecessor court upheld a PTO rule that required a particular disclaimer from applicants seeking more than one

patent on an invention. 686 F.2d 937, 945 (CCPA 1982). The Court found that the rule was "substantive in that it relates to a condition under which a patent will be granted," but noted that "[m]uch of the content of the PTO rules is 'substantive' in this respect." *In re Van Ornum*, 686 F.2d 937, 945 (CCPA 1982). As GSK rightly notes, however, the Court in *In re Van Ornum* also held that the regulation at issue comported with statutory and case law. *Id.* That case, then, is helpful to the PTO only if this Court disagrees with GSK's additional contention that the Final Rules are inconsistent with the Patent Act. As the Court will explain, GSK raises serious concerns as to whether the Final Rules comport with the Patent Act. In addition, the Court also believes that GSK has created a colorable question as to whether the Final Rules are truly substantive. Thus, the Court will find that there is a genuine possibility that GSK will succeed on this issue.

GSK's second claim, alluded to by the Court above, is that Final Rules 78, 114, 75, and 265 exceed the plain language of Title 35. As to Final Rule 78, which limits the number of continuing applications, GSK contends that Section 120 of Title 35 prohibits the PTO from limiting the number of continuing applications that may be filed. Section 120 states that later-filed applications "shall have the same effect" as pending previously-filed applications, thus allowing the former to take

the priority date of the latter. 35 U.S.C. § 120. In *In re Henriksen*, the Federal Circuit's predecessor court found that under Section 120 "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 of a chain of copending applications." 399 F.2d 253, 254 (CCPA 1968). While Final Rule 78 does not present an absolute bar on more than two continuing applications, GSK asserts that the "could not have" evidentiary burden of the petition and showing is a "de facto limit" on further continuing applications because the PTO will deny a petition in "almost all circumstances." Mem. in Support of Pls.' Mot. for a TRO and Prelim. Inj. at 19; Ex. A to Pls.' Mem. at 46769-77.

Moreover, while *In re Bogese* found that *Henriksen* did not suggest that "the PTO must allow dilatory tactics in the prosecution of applications or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution," 303 F.3d at 1368 n.6, *In re Borgese* rested on the doctrine of prosecution laches, which permits the denial of an application where the applicant delays too long in filing a continuing application. *Id. at* 1368-69; *see also Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1365-66 (Fed. Cir. 2002)("*Symbol II*")(finding that Section 120 did not abrogate the doctrine of

prosecution laches). GSK argues that, while the doctrine of prosecution laches still applies, Section 120 as interpreted in *Henriksen* prevents the PTO from crafting its own limitations to the number of continuation applications that may be filed. This sentiment is supported by *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378 (Fed. Cir. 2005)("*Symbol IV*"), where the Federal Circuit held that the doctrine of prosecution laches "should be used sparingly lest statutory provisions be unjustifiabaly vitiated." *Id.* at 1385. This holding suggests that a decision by the PTO to limit the number of continuing applications would run contrary to the mandate of Section 120.[3]

The PTO responds that Final Rule 78 is within its authority under Section 2(b)(2), is not an absolute bar to filing a third continuing application, and that the PTO will review petitions for a third application "on a case-by-case basis." Defs.' Opp'n to Pls.' Mot. at 26 n.20; Ex. 2 to Defs.' Opp'n at 46770-76. Nevertheless, the Court believes that, on balance, the law on this question tips in favor of GSK, and thus the Court

[3] A bill considered, but not passed, by Congress in 2005 suggests a similar conclusion. *See* H.R. 2795, 109th Cong., § 123 (June 8, 2005)("The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application . . . .").

will find that GSK has demonstrated a likelihood of success on this issue.

GSK further argues that 35 U.S.C. § 132 prohibits the promulgation of Final Rule 114, which governs RCEs. Section 132(b) requires that the PTO "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." 35 U.S.C. § 132(b). While GSK reads this language and finds that Congress did not grant the PTO the authority to restrict the number of RCEs that may be filed, the PTO argues that Final Rule 114 complies with Section 132 even though it requires that a petition and showing accompany the filing of a second RCE. Given the limited briefing of this issue by both parties, the Court will find that, for the purposes of this motion, neither party can claim a strong likelihood of success on this issue.

GSK makes a similar claim with respect to Final Rules 75 and 265, which limit the number of claims an applicant may file. Section 111 and 112, the relevant statutory provisions, are similar to Sections 120 and 132 in that they do not specify whether the PTO has the authority to place a limit on the number of claims an applicant may file. 35 U.S.C. §§ 111 and 112. The PTO argues that it is entitled to *Chevron* deference on this issue because of the ambiguity of Section 2(b)(2). GSK, however, has raised serious questions as to whether the PTO is entitled to

Chevron deference in this case. Nevertheles, given the limited briefing of this issue by both parties, the Court will find that, for the purposes of this motion, neither party can claim a strong likelihood of success on this issue.

The PTO justifies each of these rule changes on the grounds of administrative efficiency. GSK challenges this rationale as arbitrary and capricious because "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 statistics on the number of third or subsequent continuation applications." Mem. in Support of Pls.' Mot. for a TRO and Prelim. Inj. at 23. Judicial review of agency rulemaking under 5 U.S.C. § 706(2)(A) is guided by *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29 (1983). Under this standard, while a court "is not to substitute its judgment for that of the agency," it must still "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* at 43.

The PTO states that 2.7% of applications filed in 2006 would have required a petition and showing under Final Rules 78 and 114, amounting to approximately 11,000 continuation applications and RCEs. *See* Ex. 1 to Defs.' Mem. in Opp'n to Pls.' Mot. at A05022, A05646. The PTO explained in the final

Federal Register notice that, under the old system of unlimited continuation applications, applicants were engaging in unfocused practices that impeded the PTO's ability to effectively examine applications. Ex. 2 to Defs.' Opp'n to Pls.' Mot. at 46720. The PTO expected that limiting continuation applications and RCEs would lead to more focused prosecution and enable the PTO to apply its resources to new applications. *See id.* at 46716-20. Similarly, limiting the number of claims in each application under Final Rules 75 and 265 would accomplish the same goal. *See id.* at 46721. Furthermore, the Federal Register reflects that the PTO considered weaker alternatives but concluded that those measures would be inadequate to achieve the PTO's goals. *See id.* at 46816-23, 46824-26, 46833-34. Though the Final Rules would reduce the PTO's backlog by only 2.7% and, by their own admission, are insufficient to reduce the backlog to a reasonable level, PTO models show that they will have an impact on the backlog. *See* Ex. 1 to Defs.' Opp'n to Pls.' Mot. at A05645. Thus, the PTO's rationale appears to be sufficient to satisfy arbitrary and capricious review, and the Court will find that GSK has not shown a real likelihood of success on this issue.

GSK also takes issue with the alleged retroactive application of the Final Rules. According to GSK, the Final Rules apply retroactively because they "apply legal consequences to past events completed before the effective date [of November

1, 2007] where none attached before." Mem. in Support of Pls.' Mot. for a TRO and Prelim. Inj. at 24. Because retroactivity is not favored in the law, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988). Congress did not expressly grant the PTO those powers. *See* 35 U.S.C. § 2(b)(2).

However, the United States Supreme Court has found that a regulation is 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." *Landgraf v. USI Film Prods.*, 511 U.S. 244, 280 (1994). The PTO, citing *Landgraf*, argues that the Final Rules are not retroactive because the filing of an initial application does not create any "rights" or amount to "transactions already completed." Defs.' Opp'n to Pls.' Mot. at 33 (citations omitted). The PTO cites a number of cases dictating that patent applications do not give rise to property rights that create retroactivity concerns under *Landgraf*. *See Marsh v. Nicols, Shepher & 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."); *Brenner v. Ebert*,

398 F.2d 762, 764 (D.C. Cir. 1968)("We have considerable doubt whether appellees' allowed but unissued patent is 'property' as that term is used in the fifth amendment."); *Mullins Mfg. Co. v. Booth*, 125 F.2d 660, 664 (6th Cir. 1942)("The right of [the Defendant] to his invention while his application is pending is an inchoate right, which matures as property when the patent issues."); *De Ferranti v. Lyndmark*, 30 App. D.C. 417, at *5 (1908)("[I]n a patent no vested right of which the applicant cannot be deprived is acquired under the preliminary proceedings leading up to its issuance.").

Landgraf, however, does not limit "the presumption against statutory retroactivity to cases involving 'vested rights.'" *Landgraf*, 511 U.S. at 275 n.29. Moreover, GSK does not argue that it has rights in pending patents. Instead, GSK contends that the Final Rules "impose new duties" that did not exist under the old rules. Pls.' Reply Mem. at 17. The requirement of filing a petition and showing to justify more than two continuing applications or a second RCE and the requirement of filing an ESD under Final Rules 75 and 265 qualify as impositions of new duties with respect to already-completed transactions – here, the initial applications.

In addition, as GSK noted at oral argument, by seeking patent protection inventors like GSK sacrifice their trade secrets, and the United State Supreme Court has found that trade

secrets are property rights. *See Rucklehaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984); 35 U.S.C. § 122(b)(1). GSK, then, has voluntarily surrendered its property rights in exchange for a guarantee from the PTO that it will have a "full and fair opportunity to seek a spectrum of patent protection adequate to protect [its] investments." Brief for *Amicus Curiae* AIPLA at 3. While "an individual [that] discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret," loses that property right, *Rucklehaus*, 467 U.S. at 1002, the Final Rules retroactively alter the bargain on which inventors like GSK rely in making their decision to surrender their rights. The Final Rules thus impair GSK's right to this bargain.

Furthermore, while procedural rules often do not raise retroactivity concerns when applied to pending applications, *see Landsgraf*, 511 U.S. at 275, there remains a serious question as to whether the Final Rules even qualify as procedural. Given all of these factors, the Court will find that GSK has demonstrated a real likelihood of success on the issue.

Finally, GSK claims that Final Rule 265, which delineates the requirements of an ESD, is unconstitutionally vague because it fails to provide "any boundaries on the scope of the search." Mem. in Support of Pls.' Mot. for a TRO and Prelim. Inj. at 26. Specifically, GSK complains that 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." *Id.* at 27. According to GSK, the ESD requirement forces applicants to "search the patent literature of the entire world, as well as unspecified yet relevant 'non patent literature.'" Pls.' Reply Mem. at 18-19.

The PTO responds that, under *Marsh*, GSK does not have a vested property right in its patent application and therefore cannot bring a constitutional vagueness challenge. Defs.' Opp'n to Pls.' Mot. at 35. Regardless, the PTO also contends that the ESD requirements are sufficiently clear for applicants to be able to comply. The D.C. Circuit has found that to satisfy due process requirements, regulations "must be sufficiently specific . . . that a reasonably prudent person, familiar with the conditions the regulations are meant to address and the objectives the regulations are meant to achieve, would have fair warning of what the regulations require." *Freeman United Coal Mining Co. v. Fed. Mine Safety & Health Rev. Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997).

In the final Federal Register notice, the PTO explained that "[t]he standard for the preexamination search . . . is the same standard that the [PTO] uses to examine patent applications, which is set forth in MPEP §§ 904-904.03," and that following the

MPEP §§ 904-904.03 standard "should be sufficient" to meet the ESD requirements. Ex. 2 to Defs.' Opp'n to Pls.' Mot. at 46800. The PTO has also published further guidance documents to assist applicants in meeting these requirements. *See* Ex. 4 to Defs.' Opp'n to Pls.' Mot. at Ex. A "Guidelines for Examination Support Document ("ESD") under 37 CFR 1.265." In response, GSK notes that the need for official guidance suggests an admission of vagueness. Moreover, any guidance documents generated by the PTO outside of the notice and comment rulemaking process violate the Administrative Procedure Act. *See Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1028 (D.C. Cir. 2000). Thus, because the Court believes that GSK has raised serious concerns as to whether a reasonably prudent person would be able to comply with the ESD requirements, the Court will find that GSK has demonstrated a real likelihood of success on this issue.

Based on the difficult legal questions presented by this case, the Court will find that, in sum, the likelihood of success on the merits factor weighs in favor of GSK.

2) Irreparable harm to GSK if injunction is not granted

If the Final Rules go into effect on November 1, GSK claims that they will experience significant irreparable harm. GSK has about two thousand pending applications, the rights of which would be changed under the new rules. In particular, GSK's ability to file continuing applications for those patent

applications is truncated, and they will be unable to file the further claims they expected regarding applications for inventions that were developed based on the current rules. Because of the new limitations on continuing applications, the inventions included in pending applications will receive less protection under the law if the new rules are enacted than under the rules in place at the times the applications were filed. The harm will begin to accrue as soon as the Final Rules go into effect because GSK will have to begin making strategic decisions regarding their pending applications and the choices they make will permanently affect their rights under patent law, whether or not the Final Rules are eventually invalidated. In addition, GSK claims it will suffer from great uncertainty about how to comply with the Final Rules, and incur significant cost in creating the required examination support documentation.

GSK further argues that, if the Final Rules are not preliminarily enjoined and the Court later deems them invalid, GSK will lose a substantial amount of investment capital because it will be too late to save patent rights covering medical inventions that cannot proceed to market without strong protection. As such, potentially helpful drugs will be lost to both GSK and the public. Pharmaceutical companies like GSK give up trade secret rights regarding an invention when they choose to submit a patent application. Under the current rules, the

expectation is that the government will afford them strong, reliable patent protection in return for loss of trade secret rights. When the Final Rules go into effect, inventors lose some of the patent protection on pending applications they had come to rely upon under the current system. GSK would be unable to sue to reinstate lost patent protection or obtain monetary compensation if the Final Rules are vacated. The Fourth Circuit has found irreparable harm sufficient to warrant an injunction in cases where monetary damages are inadequate, particularly in the case of government action later found to be unlawful. *See, e.g., Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353, 361 (4th Cir. 1991); *see also Bowe Bell & Howell Co. v. Harris*, 145 Fed. Appx. 401, 404 (4th Cir. 2005) (upholding the finding of irreparable harm when "violations . . . could not be compensated by money damages alone").

The PTO cites several cases holding that the costs of complying with government regulation are not usually the kinds of irreparable harm contemplated by the legal test for a preliminary injunction. However, courts have not entirely excluded these costs from the calculation; instead, they have found that such costs are not *alone* sufficient to constitute irreparable harm under ordinary circumstances. *See, e.g., A. O. Smith Corp. v. FTC*, 530 F.2d 515, 527 (3d Cir. 1976)("[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**, would satisfy the requisite for a preliminary injunction")(emphasis added); *American Hospital Assoc. v. Harris*, 625 F.2d 1328, 1331 (7th Cir. 1980)("injury resulting from attempted compliance with government regulation **ordinarily** is not irreparable harm")(emphasis added). The mere cost of implementing otherwise reasonable regulations is not in itself irreparable harm. However, a "[plaintiff] should not be forced into the position of choosing to either violate an allegedly invalid ordinance and suffer the inherent consequences of doing so or comply with the same and suffer a loss with little hope of recovery." *Synagro-Wwt, Inc. v. Louisa County*, 2001 U.S. Dist. LEXIS 10987 (W.D. Va. 2001).

The PTO argues that GSK does not identify a specific patent application they intend to file immediately upon the implementation of the Final Rules, which the PTO offers as evidence that GSK will not experience certain harm. The PTO also explains the steps GSK might be able to take under the Final Rules which could prevent the loss of patent protection for at least one patent family. The mere necessity to make decisions or adjust patent prosecution strategy is not specific harm requiring a preliminary injunction. The PTO characterize the harms outlined by GSK as speculative and not immediate, emphasizing that GSK cannot definitely delineate certain, concrete financial

harm beyond the costs of implementing the regulations.

Although GSK cannot pinpoint an exact amount of monetary loss, the uncertainty caused by the regulations will cause harm to their investments and provide a disincentive to their filing of new patent applications for researching new pharmaceutical products. In addition, there is still some question as to whether following the complicated steps outlined by the PTO will indeed guard against lost patent protection. Finally, GSK will be unable to recover their losses if the Final Rules are ultimately determined to be invalid. Therefore, the Court finds that GSK is likely to suffer irreparable harm if the preliminary injunction is not granted.

3) The balance of hardships between the parties

The PTO claims that the balance of hardships tilts in their favor because they will have to endure the hardship caused by forcing a large organization in the midst of instituting a massive change to stop and reverse course. The PTO has spent millions of dollars training their staff and retooling their computer systems to prepare for the implementation of the Final Rules, changes that cannot be easily undone or simply placed on hold. If subjected to a preliminary injunction, they will be forced to use sub-standard systems, exposing themselves to the possibility of costly computer problems. In addition, they will continue to encounter the problems of inefficiencies and the

increased likelihood of error that the Final Rules were promulgated to fix, exacerbated by the confusion among patent filers and the likely increase in erroneous filings. They will also have to pay the costs of retraining their employees to institute the Final Rules if they go into effect on a future date.

GSK characterizes the PTO's harm as primarily sunk costs already incurred by training personnel and changing the computer systems to implement rules the organization knew might not go into effect. Any costs incurred by a delay in implementing the Final Rules would thus be merely the cost of maintaining the status quo. Additionally, GSK downplays the PTO's expectation that the Final Rules would provide a significant gain in efficiency or a reduction in backlog. GSK argues that they, by contrast, will begin to experience the irreparable harms discussed above as soon as the rules go into effect, and do not have any avenues at all for maintaining any version of the status quo when it comes to certainty about their patent protection. They will instantly suffer from uncertainty regarding the protection afforded their patents and their corresponding investment risk, in addition to the costs of attempting to comply with the Final Rules. Thus, the Court finds that, although the hardship to the PTO is not nonexistent, the uncertainty and loss of investment suffered immediately by GSK

tilts the balance of the hardships in their favor.

4) The public interest

The PTO argues that the public interest is most benefitted by the Final Rules going into effect immediately. The PTO claims that the rules promote efficiency and timeliness and are needed immediately to alleviate the harm entrepreneurs suffer because of the current system's uncertainty. In addition, patent applicants who are preparing to comply with the Final Rules will face uncertainty as to how to proceed with patent prosecution and as to which rules will govern their application during the period of an injunction.

GSK asserts that preserving the status quo while the litigation proceeds is important for maintaining stability for patent holders. Innovation is encouraged when patent holders and applicants have certainty about how their patents will be treated. The fact that three amicus briefs were filed by organizations representing a wide array of industries, all urging the Court to grant the preliminary injunction because their interests will otherwise be harmed, further demonstrates the possibility of potential immediate harm to the public if the rules are allowed to go into effect on November 1. Many companies rely upon the stable, reliable protection afforded by the current patent system in determining whether it is cost-effective to abandon their trade secret protection by pursuing a

patent. Implementation of the Final Rules changes those companies' calculus and immediately decreases their ability to pursue costly new innovations.

Allowing the implementation of rules that may or may not remain in effect is likely to cause much greater uncertainty and squelching of innovation than a preliminary injunction giving the Court time to consider the validity of the Final Rules before they go into affect. Accordingly, the Court will find that the public interest is most served by continuing the status quo and granting the TRO.

Therefore, after considering the likelihood of GSK's success on the merits, the possibility of irreparable harm to GSK if the injunction is not granted, the balance of hardships between the parties, and the public interest, the Court finds that GSK's Motion should be granted.

IV. Conclusion

For the reasons stated above, the Court will: (1) grant GSK's Motion for a Preliminary Injunction; (2) deny the PTO's Motion to Strike Exhibit E of the Memorandum in Support of GSK's Motion; (3) grant the Motion of *Amicus Curiae* AIPLA for Leave fo File its Brief in Support of GSK's Motion; (4) grant HEXAS, The Roskamp Institute, and Tikvah's Joint Motion in Support of Motion for Leave to File *Amici Curiae* Brief in Support of GSK's Motion; and (5) grant the Motion of *Amicus Curiae* Elan Pharmaceutical

Corp. for Leave to File its Brief in Support of GSK's Motion.

An appropriate Order will issue.

October 31, 2007
Alexandria, Virginia

_____/s/_____
James C. Cacheris
UNITED STATES DISTRICT COURT JUDGE