

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

TRIANAFYLLOS TAFAS,

Plaintiff,

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 the UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants.

CIVIL ACTION: 1:07cv846 (JCC/TRJ)  
and Consolidated Case (below)

SMITHKLINE BEECHAM CORPORATION,

Plaintiff,

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 the UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants.

**PLAINTIFF'S MEMORANDUM IN OPPOSITION TO  
DEFENDANTS' PARTIAL MOTION TO DISMISS**

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**PLAINTIFF'S MEMORANDUM IN OPPOSITION TO  
DEFENDANT'S PARTIAL MOTION TO DISMISS**

**PRELIMINARY STATEMENT**

Plaintiff Dr. Triantafyllos Tafas ("Dr. Tafas") submits this Memorandum in Opposition to Defendants' Partial Motion to Dismiss dated October 4, 2007 (the "Motion to Dismiss"). As set forth more below and in the accompanying Declaration of Triantafyllos Tafas dated October 26, 2007, Defendants' Motion to Dismiss (which is primarily predicated on alleged lack of standing and ripeness) is without merit and must be denied.

Defendants Jon W. Dudas and the United States Patent and Trademark Office (collectively "Defendants") seek to engender piecemeal litigation concerning the validity of the

USPTO's Revised Rules by essentially taking the extreme and impractical position that Dr. Tafas lacks standing to comprehensively challenge the ultra vires nature of the Revised Rules unless he is immediately and unconditionally impacted by every sub-element of the Revised Rules.

Focusing narrowly and exclusively on the factual and procedural particulars of Dr. Tafas' current family of patent applications, and taking an extremely cramped and self-serving view concerning what could potentially be deemed to constitute tangible harm, Defendants play "ostrich" and purport to ignore: the integrated nature of the Revised Rules, the substantial impact of the Revised Rules in terms of creating uncertainty and altering the strategy, tactics and options available to Dr. Tafas in his future course of the prosecution of his pending and future applications, the fact that Dr. Tafas is an inventor on forty-one (41) patents pending and on eight (8) U.S. issued patents, and Dr. Tafas' stated intent to continue to create and patent additional inventions.

Dr. Tafas is not required to show current harm under each and every permutation or sub-paragraph of the Revised Rules and/or the Patent Act of 1952, 35 U.S.C. §§ 1 *et. seq.*, in order to attain standing. The mere fact that the USPTO has changed the substantive criteria for patent eligibility, fundamentally altered the "rules of the game," and foreclosed Dr. Tafas' options and rights provided for by Congress causes him immediate harm including, among other things, immediately impacting how he prosecutes his pending patent applications. The harm could be no more palpable. Of course, having established injury, satisfaction of the causation and redressability elements follow as a matter of course. Invalidating the Revised Rules that are causing Dr. Tafas harm will alleviate the injury.

Dr. Tafas' challenge to the validity of the Revised Rules is ripe because it raises purely legal challenges. The peculiarities of Dr. Tafas' own personal patent prosecution history

will have absolutely no material bearing vis-a-vis the resolution of these macro-legal issues, which deal with separation of powers, scope of delegated rule-making authority and interpretation of constitutional and statutory provisions. Finally, Dr. Tafas does state a valid APA claim in his Second Count predicated on the Revised Rules being inconsistent with the Patent Clause and the Fifth Amendment of the United States Constitution.

### **STANDARD OF REVIEW**

#### **A. Motion to Dismiss for Lack of Standing and Ripeness Pursuant to Federal Rules of Civil Procedure (“FRCP”) Rule 12(b)(1)**

There are two (2) general species of standing: constitutional and prudential.

Mgmt. Ass’n for Private Photogrammetric Surveyors v. U.S., 467 F. Supp. 2d 596, 600 (E.D. Va. 2006). The party invoking federal jurisdiction bears the burden of establishing the following three (3) components of constitutional standing: (1) “that he or she suffered an actual or threatened injury that is not conjectural or hypothetical; (2) the injury must be fairly traceable to the challenged conduct; and (3) a favorable decision must be likely to redress the injury.” Miller v. Brown, 462 F.3d 312, 316 (4th Cir. 2006).

In agency rule-making challenges pursuant to 5 U.S.C. § 702 of the Administrative Procedure Act (“APA”), courts have developed a “zone of interests” test to determine whether a plaintiff has prudential standing. See *e.g.*, Clarke v. Sec. Indus. Ass’n, 479 U.S. 388, 400 n. 16 (1987). A plaintiff is required to demonstrate that the interest he seeks to protect is “arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” Nat’l Credit Union Admin. v. First Nat’l Bank and Trust Co., 522 U.S. 479, 492 (1998). This in turn requires a two (2) part inquiry: (i) “determining which interests the statute in question arguably protects,” and (ii) “determining whether the

agency action affects those interests.” Pye v. United States, 269 F.3d 459, 470 (4th Cir. 2001) (citations omitted).

For purposes of ruling on a Rule 12(b)(1) motion to dismiss for lack of standing, the court “must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party.” Warth v. Seldin, 422 U.S. 490, 501 (1975); Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). While a plaintiff may be required to provide a higher and more detailed level of evidentiary proof of standing at a later stage of the case (e.g., summary judgment), mere general factual allegations of injury resulting from a defendant’s conduct normally suffice at the initial pleading stage for purposes of Article III standing, with a presumption that such general allegations embrace any specific facts necessary to support the claim. See e.g., Bennett v. Spear, 520 U.S. 154, 168 (1997) (a plaintiff does not need show he has been damaged with any mathematical detail or certainty at initial pleading stage); Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992).

The court “may consider evidence outside the pleadings without converting the proceeding to one for summary judgment.”<sup>1</sup> White Tail Park, Inc. v. Stroube, 413 F.3d 451, 459 (4th Cir. 2005) (internal quotation marks and citation omitted); Richmond, Fredericksburg &

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<sup>1</sup> Whether the analysis required to resolve a standing challenged is confined to the complaint’s allegations or extends to evidence outside the pleadings depends on the nature of the challenge, of which there are two (2) general types: (i) a claim that the allegations, even if true, do not establish standing, and (ii) a claim that the standing allegations are not true. See e.g. Crutchfield v. U.S. Army Corps. of Eng’s, 230 F. Supp. 2d 687, 695 (E.D.Va. 2002); 5B Charles A. Wright and Arthur R. Miller, Federal Practice and Procedure, § 1350 (3d ed. 2004). The former type of challenge is typically resolved at the threshold stage without the need to consider evidence beyond the complaint’s allegations. See Crutchfield, 230 F.Supp.2d at 695. The latter type of challenge typically involves consideration of materials and evidence beyond the complaint’s four corners, and in many cases the issue is not resolved until the summary judgment stage or thereafter. See e.g., Moore’s Federal Practice § 12.30[2] (“The truth of jurisdictional allegations need not always be determined with finality at the threshold of the litigation.” (Citing Jerome B. Grubart, Inc. v. Great Lakes Dredge & Dock Co., 513 U.S. 527, 537-38 (1995))).

Potomac R.R. Co. v. United States, 945 F.2d 765, 768 (4th Cir.1991) (to obtain a Rule 12(b)(1) dismissal for lack of standing based on extrinsic evidence the moving party must establish that there is no genuine issue of material jurisdictional facts as to standing (with all the allegations in the complaint being treated as evidence and taken as true) and that defendant is entitled to a judgment as a matter of law). If there is some reasonable bona fide doubt created by the moving party as to whether the factual allegations in the complaint are truthful and/or otherwise sufficient to establish standing, the district court has the power and discretion “to allow . . . the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of standing.” Warth, 422 U.S. at 502. After this opportunity, if the plaintiff’s standing does not adequately appear from all materials of record, the complaint must be dismissed.<sup>2</sup> Id.; West Virginia Highlands Conservancy v. Norton, 137 F.Supp.2d 687, 697 (S.D. W.Va. 2001).

In assessing whether a dispute is ripe for adjudication, a court must evaluate “(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration.”<sup>3</sup> Nat’l Park Hospitality Ass’n v. DOI, 538 U.S. 803, 808 (2003) (citing Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967)).

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<sup>2</sup> Here, Defendants are not challenging the truthfulness of Dr. Tafas’ factual allegations concerning standing. The underlying facts and procedural history of Dr. Tafas’ patent filing do not appear to be in substantial dispute. Instead, the crux of disagreement between the parties centers around the legal inferences to be drawn from the facts (i.e., whether the type of harm is sufficient and immediate enough to provide standing). Dr. Tafas believes he has produced enough evidence to carry his burden even at summary judgment. However, even if the Court were to disagree with this assertion, Dr. Tafas still should be afforded another opportunity to amend his pleading and/or to provide the full measure of evidence necessary at the next stage of litigation.

<sup>3</sup> A court must grant the plaintiff the benefit of all favorable inferences that may be drawn from the facts alleged in the complaint and such allegations must be construed whenever possible in plaintiff’s favor. Lemon v. Harvey, 448 F.Supp.2d 97, 101 (D. D.C. 2006). In evaluating a Rule 12(b)(1) ripeness challenge, the same procedural standard for deciding a Rule 12(b)(1) standing

**B. Motion to Dismiss for Failure to State a Claim Pursuant to FRCP Rule 12(b)(6).**

In deciding whether to grant a motion to dismiss for failure to state a claim under Rule 12(b)(6), the factual allegations in a plaintiff's complaint must be accepted as true, and the motion should only be granted if it appears beyond doubt from the four corners of the complaint that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief. See e.g., Terry v. Director, Complaint Adjudication Div., U.S. E.E.O.C., 21 F. Supp. 2d 566, 568 (E.D. Va. 1998).

**ARGUMENT**

**Point I**

**PLAINTIFF HAS ADEQUATELY PLED HIS STANDING TO CHALLENGE THE USPTO'S REVISED RULES**

Dr. Tafas has suffered actual or threatened harm sufficient to afford him standing to challenge the USPTO's Revised Rules -- frequently referred to by the USPTO as Final Rules 75, 78, and 114 (and which are sometimes collectively referred to herein, and in Dr. Tafas' Amended Complaint, as the "Revised Rules"). In order to have standing at this initial pleading stage of the case, Dr. Tafas need only plead generalized allegations of actual or threatened harm as a result of the Revised Rules, which might be avoided by a favorable decision in this action by the Court (*i.e.*, an invalidation of the Revised Rules). Here, Defendant's Motion to Dismiss must be denied because the Amended Complaint and the Tafas Declaration are replete with specific references to actual or threatened harm to Dr. Tafas directly flowing from the USPTO's promulgation of the Revised Rules, which allegations of injury must be taken as true. (See Amended Complaint, ¶¶ 21-33, 56, 64, 83; 85 and 86; Tafas Declaration, ¶¶ 18-45).

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motion applies. See Int'l Acad. of Oral Med. & Toxicology v. North Carolina State Bd. of Dental Exam'rs, 451 F.Supp.2d 746, 749 (E.D. N.C. 2006).

**A. Dr. Tafas Has Sufficiently Alleged Injury from Final Rule 78 and 114.**

Defendants incorrectly assert that Dr. Tafas has not been injured by Final Rules 78 and 114 because it is entirely “speculative” whether he will file, could file or will file the requisite, continuation application or continuation-in-part application or voluntary divisional application so as to actually trigger the need to meet the requirements of Final Rule 78. (Def. Mem. at pp. 16-18). Defendants similarly erroneously assert that Dr. Tafas lacks standing to challenge the USPTO’s Revised Rules concerning filing Requests for Continued Examination (“RCE”) claiming that none of Dr. Tafas’ patent applications are sufficiently “mature” to make him immediately eligible to file an RCE. (Def. Mem. at pp. 21). In sum, Defendants are attempting to set up a “straw man” argument that no harm may occur until Dr. Tafas is actually compelled to comply with one of the new USPTO’s petition or filing requirements -- completely ignoring the immediate practical harm imposed upon Tafas and the entire patent community. (Amended Complaint, ¶¶ 21-33; Tafas Decl., ¶¶ 18-45). As discussed below, Dr. Tafas has suffered immediate injury as a result of the Revised Rules.

First, Dr. Tafas has alleged direct and threatened non-conjectural injury to himself as a result of Final Rules 78 and 114. (Amended Complaint, ¶¶ 21-33, 56, 64, 83, 85, 86). These allegations must be taken as true for purposes of the Court deciding this Rule 12(b)(1) motion, which taken alone is sufficient to mandate denial of Defendants’ standing arguments. (See Standard of Review infra). For example, Dr. Tafas identifies a myriad of actual or imminently threatened injuries in his Amended Complaint including, without limitation, a restriction of his statutory right to file unlimited continuation applications; a significant reduction in the the likelihood that he will be successful in obtaining the fullest possible patent protection for his inventions; possible risk of loss of confidentiality protections afforded by the Patent Act before the imposition of the Revised Rules and, by extension, a resulting increased risk of

misappropriation or copying by third-parties; loss of other rights under existing Patent Act provisions; additional costs and burdens in complying with the new rules; the creation of disincentives to inventing and utilizing the patent process; and, injury from the substantial uncertainties created as to the valuation of Dr. Tafas' patent portfolio and resulting negative impact on his ability to raise capital. (See Amended Complaint, ¶¶ 21-34; 56, 64, 83 and 86).

Second, Dr. Tafas is not a gratuitous intermeddler seeking an abstract advisory opinion from this Court. Dr. Tafas has filed numerous patent applications in the past; presently has patent applications pending with the USPTO; and, based on his past history and stated intention, there is every reason to believe that Dr. Tafas will file new patent applications with the USPTO in the future (as well as any continuation applications he deems necessary and appropriate with respect to his pending application). (See Amended Complaint, ¶¶ 1; Tafas Decl. at ¶¶ 16, 17).

All of Dr. Tafas' present and future filed applications are directly subject to and regulated by the USPTO's rules of practice including, without limitation, the new Revised Rules now at issue. The fact that Dr. Tafas is regulated by, and his rights restricted by, the Revised Rules is true regardless of whether or not Dr. Tafas actually subsequently files a petition with the USPTO seeking to exceed the two (2) continuation limit. Again, Dr. Tafas is adversely impacted, among other ways, in terms of having to take additional costly steps in preparing and prosecuting his pending patent applications. For example, it is necessary for Dr. Tafas to adopt different prosecution strategies and tactics so as to try to avoid, if possible, from having to petition the USPTO for relief under the new Revised Rules. (Tafas Decl. ¶¶ 70). Dr. Tafas is immediately hurt, among other ways, by the increased costs and additional steps necessary to comply with the new Rules, as well as by the uncertainty created in terms of whether additional

continuations will be reasonably obtainable via petitions to the USPTO should they subsequently prove to be needed in a manner that is not cost prohibitive. (Tafas Decl. ¶¶ 38, 66; Amended Complaint ¶¶ 21-34).

It is well established in cases like this that the issue of standing and the issue of ripeness often “boil down to the same question.” MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 772 n.8 (2007). The standard of review is more lenient in cases such as this where the party seeking such relief -- like Dr. Tafas here -- can demonstrate a direct, continuous, and ongoing relationship with party or agency and a substantial likelihood of harm, though avoidable it may be, courts will generally find the challenge to be ripe and the party has standing to raise his or her claims. See MedImmune, 127 S. Ct. 764 (holding Declaratory Judgment Act claim justiciable even though party could avoid patent infringement liability); Abbott Labs., 387 U.S. at 149 (allowing regulated entities to preemptorily challenge Food and Drug Administration rules due to the hardship associated with withholding judicial consideration); Better Gov’t Ass’n v. Dept. of State (“BGA”), 780 F.2d 86, 95-96 (D.C. Cir. 1986) (allowing parties with history of filing Freedom of Information Act “FOIA” fee waiver requests, and the expressed intent to do so in the future, to challenge federal guidelines, even though their original claims had been rendered moot). Generally, a rule of agency procedure will be deemed ripe on a facial challenge. Hudson v. Fed. Aviation Admin., 192 F.3d 1031, 1035 n.3 (D.C. Cir. 1999).

It is established that regulatory actions may “give[] rise to legal rights and consequences” when a party has “a realistic fear . . . of being subject to [a] regulation.” Manufactured Housing Inst. v. EPA (“MHI”), 467 F.3d 391, 398 (4th Cir. 2006). In MHI, an association was found to have standing to challenge a change in the applicability of Safe Drinking Water Act rules on the grounds that mobile home parks were not granted an exception

given to apartment buildings *even though this rule left them in exactly the same position as before the regulation was adopted.* Id.

The elemental fact is, petitioners allege that they want to sub-meter but that the policy's failure to treat them like apartment-building owners prevents them from doing so, and they have sworn to this *chilling effect*. It is true that the record is silent regarding the extent of financial cost to petitioners. But EPA's patent regulatory exclusion from the protected class is more than the needed "decision as to whether review will be sought in the hands of those who have a direct stake in the outcome."

Id. (quoting Sierra Club v. Morton, 405 U.S. 727, 740 (1972)) (emphasis added). The court found the parties' injuries to be substantial, holding that they "were not merely 'value preferences' under Sierra Club."<sup>4</sup> Id. (citation omitted).

In this case, Dr. Tafas' injuries are direct and substantial, and even more so than the MHI petitioners. The USPTO has changed the regulatory environment in which Dr. Tafas operates for the worse (instead of granting other parties the benefit of a more favorable environment). There can simply be no doubt that Dr. Tafas has a "direct stake" in the Revised Rules, which he will be required to follow in prosecuting his current and future applications.

Nor is it relevant whether Dr. Tafas' current family of patent applications runs immediately afoul of every Revised Rule or Patent Act provision at issue. Courts have held that parties may suffer a "continuous injury due to a [mere] deprivation of a statutory entitlement."<sup>5</sup>

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<sup>4</sup> The "value preferences" referred to by the Supreme Court in Sierra Club were an organization's generalized interests in "the use of natural resources," which it contrasted with types of interests expressed by "those who have a direct stake in the outcome" of a rule at issue. Sierra Club, 405 U.S. at 736, 740.

<sup>5</sup> In BGA, non-profit associations were found to have standing to challenge "a set of guidelines promulgated by the Department of Justice" and utilized by various federal agencies in deciding whether to grant fee waiver applications under the FOIA on the grounds that they did not comport with the law. 780 F.2d at 88. The court found standing in BGA even though plaintiffs' challenge to a specific fee waiver denial was mooted by a reconsideration and grant of the applications subsequent to the filing of suit. Id. at 91. Though the immediate injury abated, the parties were still found to have suffered constitutional injury because, as "frequent FOIA

BGA, 780 F.2d at 95; Jem Broadcasting Co. v. FCC, 22 F.3d 320, 325 (D.C. Cir. 1994) (holding that procedural rules of prospective effect create injury upon promulgation to all parties to which they are “applicable as a general matter” whether or not the party had an application impacted by the rules at that time).

Courts recognize that parties may be injured by regulations of prospective effect even when a party may not be immediately affected by their application for the simple expedient that the courts do not expect parties to undertake the impossible or subject themselves to penalties or greater harm by doing what the regulations disallow.<sup>6</sup> See MedImmune, 127 S. Ct. at 772 (“[W]here threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis of the threat—for example, the constitutionality of a law threatened to be enforced”).

Like the seminal case on standing, Lujan, many of the other cases Defendants rely on are distinguishable from the present facts because they involve the issue of “third party” standing, or a situation in which the party is complaining of the government’s conduct with respect to some other party not in court. As such, these are inapposite here because Dr. Tafas is directly affected by all the provisions of the rule at issue and is asserting his own claims. As an

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requesters,” they would be subject to “these purportedly objectionable standards in the future.” *Id.* The *ultra vires* change in the regulatory framework under which Dr. Tafas will be forced to prosecute his present and future applications, along with the loss of rights provided him under the Patent Act, represents a “continuing injury” similar to that in BGA that confers Dr. Tafas standing to challenge all the rules at issue. (Tafas Dec. ¶ 71).

<sup>6</sup> For example, in Abbott Labs., the Supreme Court held drug companies and their associations had standing to mount a Declaratory Judgment Act challenge to labeling requirements without having to first violate the rules. 387 U.S. at 148-54. Although discussing the issue in terms of finality, the Court stated, “regulations have the force of law before their sanctions are invoked . . . and the expected conformity to them causes injury cognizable by a court of equity.” *Id.* at 150 (quoting Columbia Broadcasting Sys. v. United States, 316 U.S. 407, 418-419 (1942)). Noting the “direct effect on the day-to-day business of” the regulated entities, a regulation’s issuance “puts petitioners in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.” *Id.* at 152 (footnote omitted).

inventor with multiple patents, live patent applications, and the sworn intent to file future applications, this case presents facts that are a far cry from those in Lujan.<sup>7</sup> (Tafas Decl., ¶¶ 9, 16-17).

The other line of cases Defendants cite to stand for the inarguable proposition that standing is determined on a “claim-by-claim” bases. (See Def.’s Mem. at 15-16). Here, the USPTO seeks to adopt a “divide and conquer” strategy and to effectively “balkanize” Dr. Tafas’ claims, asserting that each individual sub-section and sub-paragraph in the Revised Rules asserted to be illegally promulgated must affect Dr. Tafas immediately and personally in order for him to be heard.

Even at face value, the cases cited by Defendants do not present a reasonable parallel for the case at bar. Two of these cases, FW/PBS, Inc. v. City of Dallas, 493 U.S. 215 (1990), and CAMP Legal Defense Fund v. City of Atlanta, 451 F.3d 1257 (11th Cir. 2006), involved challenges to city ordinances in the context of First Amendment claims. Allen v. Wright, 468 U.S. 737 (1984), involves civil rights challenges to federal tax provisions that ground themselves on the rocky shoals of generalized grievance standing cases. In FW/PBS and CAMP, those courts found that the plaintiffs did not have standing to assert specific claims

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<sup>7</sup> In Lujan, environmental plaintiffs complained of Secretary of the Interior’s failure to consult with other government agencies under Section 7(a)(2) of the Endangered Species Act with respect to federally funded projects oversees, and the underlying policy that disclaimed the Secretary’s duty to undertake consultation in those circumstances. 505 U.S. at 557-58. In a challenge to this rule by an organization with only a second or third degree interest in the eventual impacts the rule could have, the Supreme Court announced heightened standards of pleading and proof with respect to the elements of standing in order adduce that the plaintiff suffers actual injury, and not just that that party as merely a “special” or “cognizable” interest in the subject. Id. at 563. The Lujan Court, however, distinguished this third-party situation from one in which “the plaintiff is himself an object of the action (or forgone action) at issue [where] there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.” Id. at 562-63.

because (at least on the record before the courts) it did not appear that the specific ordinances affected any party to the suit.<sup>8</sup> See, e.g., FW/PBS, 493 U.S. 215; CAMP, 451 F.3d 1257.

Here, the questions before this Court are of a fundamentally different nature. The Revised Rules are not narrowly drawn ordinances applicable to a very small and discrete group. Instead, they are sweeping rules of general application to all present and future patent applicants. As an inventor and present and future patent applicant, Dr. Tafas is plainly *subject to* all the USPTO's rules applicable to patent applicants, even if, as to any particular application, not every USPTO regulation will always apply at any one time (e.g., rules on divisional applications and continuing applications only come into play later in the process than the rules as to what constitutes a valid initial filing). In fact, the mere existence of the new Revised Rules forces patent applicant to undertake a whole different strategic and tactical response with respect to filing an application due to the significant constraints and considerations that must be made. (Tafas Decl. ¶ 70-71). This is an immediate impact which constitutes harm sufficient to confer standing. See BGA, 780 F.2d at 94 (deprivation of "statutory entitlements" causes a "continuing injury").

As is reflected in the USPTO's own supporting memorandum, the USPTO's objective in promulgating these new rules was not simply to make new rules concerning the *mechanics* or process of filing continuation applications, but rather to substantively limit the number of continuation applications that could or would be filed by deterring and/or preventing

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<sup>8</sup> This is the aspect of the cases that Defendants seize on as being superficially similar to this case, *i.e.*, that "[w]here a plaintiff challenges multiple provisions or rules, a court must analyze whether the plaintiff has standing to challenge each provision or rule separately." Def.s' Mem. at 15 (citing cases). In fact, these cases both say that when mounting a facial challenge to an ordinance as being constitutionally overbroad, one may only attain standing to make that facial claim if the law or ordinance could or does directly affect that individual or entity. FW/PBS, 493 U.S. at 215; CAMP, 451 F.3d at 1257.

applicants such as Dr. Tafas from exercising their statutory rights to file unlimited continuations under the Patent Act:

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 [USPTO's] ability to examine newly filed applications. Consequently, in January 2006, the USPTO proposed new rules for filing continuation applications and for presenting claims.

Def. Mem. at p. 8 (Emphasis Added).

While the USPTO implies that it is merely creating rules of procedure for the efficient submission of continuation applications, Dr. Tafas has alleged (and it is otherwise quite transparent) that the USPTO's overriding purpose in passing the Revised Rules was to substantively limit the number of continuation applications and claims that patent applicants would be permitted to file and/or could afford to file under the onerous new rules. (Amended Complaint, ¶¶ 16-20; Tafas Decl., ¶¶ 62-63). In order to accomplish its objective, the USPTO deliberately crafted its Revised Rules to immediately restrict the statutory rights of all present and future applicants to file unlimited continuation applications. In other words, the loss of rights and resulting injury to all patent applicants is the very sin qua non of the Revised Rules. This divestiture of statutory rights caused an immediate loss of rights and consequential injury to Dr. Tafas, as well as to every other inventor who regularly utilizes the U.S. patent system and/or will do so in the future. (See Tafas Decl. at ¶ 18-32).

Third, Dr. Tafas is already at the maximum number of continuation applications he may file after November 1, 2007 with respect to certain of his applications without the need to file a petition under Final Rule 78. (Amended Complaint, ¶¶ 1; Tafas Decl., at ¶¶ 16-18). Thus, Dr. Tafas is indisputably already subject to and immediately injured by the provisions of Rule 78. As of the November 1, 2007 effective date, Dr. Tafas will be required to obtain the permission of the USPTO to do that which he formerly had on absolute and unconditional right

to do. The USPTO has made conditional that which was formerly unconditional. Moreover, again the USPTO has presented no persuasive authority to support its bald contention that Dr. Tafas may not pausibly be deemed injured unless and until he actually attempts to utilize the new USPTO continuation procedures.<sup>9</sup>

The USPTO's suggestion in its memorandum (p. 12) that Dr. Tafas might somehow be able to mitigate his damages flowing from the new continuation restrictions by filing a so called suggested restricted requirement -- even if theoretically accurate -- does not alter the fact that the USPTO has unlawfully divested Dr. Tafas of his statutory rights. If anything, the USPTO's suggestion of different alternatives or methodologies that a patent applicant might be able to avail himself of in order to reduce the hardship flowing from the new Revised Rules only confirms what Dr. Tafas and other outraged members of the patent community have been so loudly complaining about -- which is that they will need to go to considerable effort and expense now to attempt to mitigate and avoid the harsh effects of the new restrictions in the Revised Rules. Even then, it is still doubtful at best that Dr. Tafas will be able

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<sup>9</sup> Defendants also contend that Dr. Tafas lacks prudential standing concerning his challenge to Rule 114 asserting that Dr. Tafas' presently pending patent applications are not yet sufficiently advanced in the USPTO process so as to presently qualify him to file a request for continued examination or RCE. (Def. Mem. at p. 21). Thus, the USPTO again reasons (erroneously) that Dr. Tafas has not yet been adversely impacted by the USPTO's new restriction on his statutory right to file RCE's under Section 132(b) of the Patent Act (35 U.S.C. § 132(b)). Again, as a person with pending patent applications, Dr. Tafas is directly regulated both by the Patent Act and the USPTO's procedural rules of general application. Here, both Final Rule 78 and 114 impose new forms of substantive restriction, upon Dr. Tafas (and all other patent applicants) where none previously existed. As previously stated, the raison d'être of these rules is by very definition to (a) impose new substantive conditions for eligibility to receive a patent; and/or (b) to take away substantive rights from Dr. Tafas and other inventors that are provided for under Congressional statutes. In fact, the Revised Rules would not have the effect intended by the USPTO of reducing the aggregate number of future continuation applications filing that must be processed by the USPTO unless they operated to divest patent applicants of their prior right to file an unlimited number of continuations. Thus, Dr. Tafas is clearly within the "zone of interests" regulated by the Revised Rules providing prudential standing.<sup>9</sup> See Nat'l Credit Union, 522 U.S. at 492.

to fully and cost-effectively obtain the level of patent protection intended by Congress in light of the Revised Rules. (See Tafas Decl. at ¶¶ 66).

Finally, Defendants have improperly sought to dismiss various sub-paragraphs from paragraph 56 of the First Count and, in the process, have incorrectly confused what is needed to establish standing with the ultimate merits of the case. Standing simply requires some type of palpable actual or threatened injury that makes the plaintiff a proper person to assert the underlying claim. Standing (or lack thereof) turns on whether a plaintiff pleads and demonstrates an injury, after which the Court may proceed to consider the merits.

Here, the “claim” in Count One of the Complaint is a challenge by Dr. Tafas to the Revised Rules. In order to establish standing Dr. Tafas need only plead that he has been injured by the Revised Rules, which he has done. In order to substantively establish his claim on the merits, Dr. Tafas will need to prove not only that he has been injured, but also that the Revised Rules were promulgated in an ultra vires manner and/or contrary to or inconsistent with law. The purpose of paragraph 56 in the Amended Complaint is not to address or satisfy “standing” requirements and/or set forth separate claims for relief, but instead merely to recite the different ways that the Revised Rules were “contrary to law” so as to enable Dr. Tafas to carry his burden of proof on the merits of his APA claim.<sup>10</sup> (See Amended Complaint, ¶¶ 55-57).

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<sup>10</sup> Even assuming arguendo that Rule 12(b)(1) could be used as a mechanism to excise selected paragraphs of a single count (which is dubious at best), Dr. Tafas still has standing so long as he has been generally injured by the Revised Rules. Dr. Tafas is not restricted to citing to only specific “inconsistent” provisions of the patent statute that Dr. Tafas is directly effected by and may freely cite as many inconsistencies as might exist. Thus, Defendants may not properly seek to treat the individual sub-paragraphs within paragraph 56 as separate “claims” (each paragraph representing is merely one (1) of the sub-elements of the overall APA claim) and the Court should not dismiss interspersed sub-paragraphs within Count One due for lack of standing.

**B. Dr. Tafas Has Sufficiently Alleged Injury from Final Rule 75.**

Significantly, Defendants concede that Dr. Tafas has constitutional standing to challenge Final Rule 75, which purports to limit a patent applicant to filing a total of five (5) independent claims and twenty-five (25) total claims for examination unless the applicant files a so called “examination support document” or “ESD”.<sup>11</sup> (Def. Mem. at pp. 11-12 and 22). Nonetheless, Defendants claim a lack of prudential standing stating that Dr. Tafas is not immediately faced with the need to file an ESD with regard to any of his presently pending patent applications and speculating that he may not ultimately be faced with such a need based on the present procedural status of his pending patent applications.

As concerns prudential standing, the threshold showing that must be made is fairly minimal, which is merely that *Dr. Tafas is a person regulated under Rule 75* and the other Revised Rules. See Nat’l Credit Union, 522 U.S. at 492 ; Pye, 269 F.3d at 469-70. Again, prudential standing to challenge agency action in court in the APA context exists if “the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute . . . in question.” Nat’l Credit Union, 522 U.S. at 492. Parties who are directly regulated under a challenged statute or rule enactment, such as Dr. Tafas here, have routinely been viewed as being with the zone of interests necessary for prudential standing. See e.g., TAP Pharmaceuticals v. U.S. Dept. of Health & Human Serv., 163 F.3d 199, 203 (4th Cir. 1998).

This showing that Dr. Tafas is within the zone of interests regulated by the Revised Rules is easily made because he has pending patent applications which are subject to the

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<sup>11</sup> While Defendants do not appear to be challenging Dr. Tafas’ constitutional standing to challenge Rule 75, standing clearly exists based on all the same considerations discussed previously with respect to Dr. Tafas’ challenges to Rules 78 and 114.

requirements and limitations imposed by the Revised Rules -- the very purpose of which were to substantively limit Dr. Tafas and others from exceeding the 5/25 claims limit requirement by imposing a cost-prohibitive ESD requirement that would, as a practical matter, act as almost complete deterrent to any patent applicant trying to exceed the arbitrary numerical 5/25 claims limitation imposed by the USPTO.<sup>12</sup> (See Amended Complaint, ¶¶ 19, 26, 30, 56; Tafas Decl., ¶¶ 16, 17).

Moreover, Defendants' implication that Dr. Tafas' prudential standing under Rule 75 should be viewed in isolation from the operation of other Revised Rules should not be credited, among other reasons, because Defendants themselves admit that the operation of Rule 75 works in tandem with Rule 78. (See Def. Mem. at pp. 11, 22-23). In enacting and issuing the Revised Rules on August 21, 2007, the USPTO made it clear that the Rules were carefully considered, integrated and part of a comprehensive "reform." Anyone substantially adversely effected by the Revised Rules (in whole or in part) should be permitted to file a single lawsuit and obtain a determination in an efficient and effective manner as to whether the USPTO's integrated and inter-woven rule enactment are ultra vires and/or contravene the Patent Act. It makes little sense from an efficiency or judicial economy perspective to apply prudential

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<sup>12</sup> Dr. Tafas is similarly squarely regulated by and directly within the zone of interests of the Congressional statutes setting forth the substantive requirements that must be met by patent applicants in order to be entitled to the issuance of a patent as of right (35 U.S.C. § 1 et. seq.). In exercising its plenary constitutional power to make laws concerning under what circumstances patents will issue, Congress plainly intended to benefit patent applicants such as Dr. Tafas. Congress made it clear in 35 U.S.C. § 2 that the USPTO's rulemaking power was procedural in nature and was limited to enacting only procedural rules that were not inconsistent with applicable law. (See also Point III, infra). Here, the USPTO has self-servingly imposed oppressive new substantive requirements for patent eligibility without any authority. To make matters worse, the new substantive requirements conflict with various provisions of the Patent Act. When the USPTO in its rule-making enacts substantive rules that are at odds with and materially alter the eligibility requirements necessary to obtain a patent set by Congress, this plainly causes direct injury to present and future patent applicants by divesting them of their statutory rights. As such, Congress must have intended for judicial review under the APA, 5 U.S.C. § 702.

standing considerations to deny standing here, which again would only encourage piecemeal, *ad hoc* and inefficient litigation, as opposed to facilitating an efficient comprehensive adjudication concerning the validity (or lack thereof) of the Revised Rules.

**C. Dr. Tafas Has Standing to Assert a “Logical Outgrowth” Claim.**

First, Defendants’ motion to dismiss Dr. Tafas’ so called “logical outgrowth” claim in Count Three for lack of standing may not be granted because Dr. Tafas has already established sufficient injury to have constitutional and prudential standing to challenge Final Rule 78.

Second, Defendants acknowledge that a logical outgrowth claim may give rise to standing where the procedural norm is designed to protect some threatened concrete interest of the plaintiff and rely on Animal Legal Defense Fund, Inc. v. Glickman (“ALDF”), 204 F.3d 229, 236 (D.C. Cir. 2000)(“ALDF”) as somehow illustrative that Dr. Tafas similarly lacks the type of concrete injury found missing in ALDF. (See Motion to Dismiss at pp. 25-26). ALDF is, however, easily distinguishable and inapposite. Unlike the plaintiff in ALDF, a procedural injury to Dr. Tafas’ concrete interest is one of the ultimate basis of his standing. ALDF, 204 F.3d at 236 (citation omitted). Tafas falls squarely within the rationale of Hodges v. Abraham, 300 F.3d 434, 444 (4th Cir. 2002), which makes clear that a plaintiff has procedural standing where, as here, the regulatory procedures being challenged are designed to protect some threatened concrete interest which is the ultimate end basis for a plaintiff’s standing.<sup>13</sup> Dr. Tafas, as an

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<sup>13</sup> Because Dr. Tafas is entitled to a procedural right, he can establish Article III standing “without meeting all the normal standards for redressability and immediacy.” Hodges, 300 F.3d at 444 (quoting Lujan, 504 U.S. at 572 n.7). “A plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result.” Nat’l Parks Conservation Ass’n v. Manson, 414 F.3d 1, 5 (D.C. Cir. 2005) (quoting Sugar Cane Growers Coop. v. Veneman, 289

inventor, a holder of numerous patents, and someone who continues to invent and patent his inventions, Dr. Tafas has a concrete interest in the Final Rules which regulate the procedures by which he will prosecute his patents both now and into the indefinite future. (Tafas Decl. ¶¶ 16, 17). Such an interest is not a “general interest common to all members of the public.” Ex parte Levitt, 302 U.S. 633, 633 (1937).

The USPTO’s contention that Dr. Tafas must have a divisional application or a specific international application on file with USPTO in order to have a concrete interest and, therefore, procedural standing to bring the claims in paragraphs 71(c), (e), and (f), is unduly restrictive. See Def.s’ Mem. at 26-27. Indeed USPTO does not cite any authority to support their contention. See id. at 26-27. Again, Dr. Tafas is an inventor who is continually developing new inventions and patents are essential to protect his inventions. Thus, that Dr. Tafas intends or is considering filing the divisional and international applications is sufficient to establish his procedural standing to bring the claims in paragraphs 71(c), (e), and (f). (Tafas Decl., ¶¶ 16, 17).

In sum, Dr. Tafas has standing to bring the claims in paragraphs 71(c), (e), and (f) of the amended complaint because his concrete interests were injured by USPTO’s failure to comply with the notice and comment provisions of the APA. Therefore, USPTO’s 12(b)(1) motion to dismiss Dr. Tafas’ claims in paragraphs 71(c), (e), and (f) of the amended complaint must be denied.

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F.3d 89, 94-95 (D.C. Cir. 2002)). Plainly, the notice and comment procedures under section 553 of the APA were connected to the Final Rules. See Id. Finally, Dr. Tafas’ allegations are within the zone of interests that the Patent Act is intended to protect. See Hodges, 300 F.3d at 444 (stating that a plaintiffs’ concrete interests “must be one that falls within the ‘zone of interests’ that the challenged statute is designed to protect”). USPTO does not dispute this.

## Point II

### **PLAINTIFF'S CLAIMS ARE RIPE FOR JUDICIAL REVIEW**

The pure legal question as to whether Defendants acted in an *ultra vires* manner and in violation of the APA in promulgating the Revised Rules is plainly ripe for review. “[T]he doctrine of ripeness is one of indefinite contours, especially when considered in conjunction with a declaratory judgment action.” Warner Cable Communications, Inc. v. Borough of Schuylkill Haven, 784 F.Supp. 203, 206 (E.D. Pa.1992). While the Declaratory Judgment Act allows a court to issue a judgment before an injury is accomplished, there must be an actual controversy at issue. See Delavigne v. Delavigne, 530 F.2d 598, 601 (4th Cir.1976). “[A] declaratory judgment may not be given for a purely hypothetical situation [or as] . . . an advisory opinion.” A.S. Abell Co. v. Chell, 412 F.2d 712, 719 (4th Cir. 1969).

A ripeness determination basically involves the following two-prong inquiry: “(1) is the issue fit for judicial review, and (2) will hardship fall to the parties upon withholding court consideration.” West Virginia Highlands Conservancy, Inc. v. Babbitt, 161 F.3d 797, 800 (4th Cir. 1998); Arch Mineral Corp. v. Babbitt, 104 F.3d 660, 665 (4th Cir. 1997). Typically, a case “is fit for judicial decision where the issues to be considered are purely legal ones and where the agency or action giving rise to the controversy is final and not dependant upon future uncertainties or intervening agency rulings.” Arch Mineral Corp., 104 F.3d at 665 (internal citations omitted). “[A] case is fit for judicial decision where the issues to be considered are purely legal ones and where the agency rule or action giving rise to the controversy is final and not dependent upon future uncertainties or intervening agency rulings.” Charter Fed. Sav. Bank v. Office of Thrift Supervision, 976 F.2d 203, 208 (4th Cir.1992). The purpose of the “‘hardship to the parties’ analysis is to ascertain if the harm that deferring review will cause the petitioner[ ]

outweighs the benefits it will bring the agency and the court.” Eagle-Picher Indus., Inc. v. EPA, 759 F.2d 905, 918 (D.C.Cir.1985).

Applying this standard, Dr. Tafas’s claims are plainly ripe for review<sup>14</sup> and the basis for decision in BGA is equally applicable in this matter. Again, the core issues for decision are purely legal without any need for further factual development as were the regulations at issue in BGA alleged to be. 780 F.2d at 92. Second, the USPTO’s action has taken its final form as was the case in BGA. Moreover, and as explained in more detail below, Dr. Tafas would suffer the same type of “hardship” as the parties in BGA if this case is deferred, because the new Revised Rules are and will continue to affect his “primary conduct” in a manner contrary to the congressionally-expressed intent of the Patent Act.

The key factors that the BGA court found persuasive in determining that appellants’ claims were ripe included the fact that they were “frequent FOIA requesters” and that “the Government clearly intends to apply these purportedly objectionable standards to FOIA fee waiver requests in the future.” 780 F.2d at 91. Thus, the fact that the appellants sufficiently demonstrated a record of availing themselves of the rules in the past, accompanied by clearly expressed intent to do so in the future raised their claims to a level of immediacy sufficient to

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<sup>14</sup> In many respects, the case at bar is strikingly similar to that in BGA. There, the government argued that because appellants’ claims regarding the denial of a fee waiver request was mooted by a subsequent grant of the request, that a challenge to overarching standards for evaluating future such requests was not ripe. BGA 780 F.2d at 91. The issue, therefore, was the same as Defendants raise here; specifically, that application of the rules at issue lay in the future and, therefore, ostensibly, “the ‘effects’ of [USPTO’s] new rules [have not] been “felt in a concrete form.”” Defs’ Mem. at 25 (quoting Abbott Labs., 387 U.S. at 148-49). While the BGA court agreed the denial of the specific request was moot, it found, however, that “appellants’ other arguments concerning the facial validity of the” guidelines and regulations at issue not moot and ripe for consideration. Id. at 91-92.

create ripe, justiciable issues.<sup>15</sup> In the present case, not only does Dr. Tafas meet this test, but he actually has current live applications which are subject to many of the rules at issue.

Furthermore, the BGA court found sufficient hardship to satisfy the second prong of the ripeness test when an agency eliminates a right provided for by statute, as is alleged here with respect to the rules at issue, “then an authoritative rejection of the blanket nature of that entitlement *is a concrete injury even if the impact on any particular [party] is not immediate.*” AFGE, 750 F.2d at 145, quoted in BGA, 780 F.2d at 94. And because this injury is immediate – *i.e.*, that the USPTO’s illegal actions alleged in this case “constitute[] an impairment of rights [under the Patent Act], not the mere threat of future impairment,” id. – it is clear that Dr. Tafas would suffer hardship if review of his claims were delayed.

### Point III

#### **PLAINTIFF STATES VALID CONSTITUTIONAL CLAIMS**

##### **A. Dr. Tafas Has Stated A Valid Claim under the Patent Clause.**

In Count Two of his Amended Complaint, Dr. Tafas alleges that the Revised Rules promulgated by the USPTO, which is part of the Executive Branch, are inconsistent with

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<sup>15</sup> These facts distinguish this case from Regional Mgmt. Corp. v. Legal Services Corp., 186 F.3d 457 (4th Cir. 1999), relied upon by Defendants. (Def.’s Mem. at 24). In that latter case, which also involved an agency’s FOIA policies, the court found that the policy under which plaintiff’s mooted denial of a FOIA request was made was not “fully developed,” was unique in its particular application at issue in the case, the party raising the legal challenge had only made this one request, and there were no facts to suggest that it would ever have cause to file another such request. *Id.* at 465. Under these circumstances, it was rational to decide that the issues were not ripe (and, although the court did not state it in these terms, that the plaintiff also had no standing to raise them), because the policy might evolve, decisions on whether to deny or grant a request would be fact based, and the issue may never arise again. In BGA and this case, by contrast, the rules are crystal clear and straight-forward, and the parties raising the claims frequently availed themselves of the procedures at issue and intend to continue to do so for the foreseeable future.

Article I, section 8, clause 8 of the U.S. Constitution (the “Patent Clause”) (Amended Complaint, Second Count, ¶ 60). The Patent Clause provides in pertinent part as follows:

The Congress shall have the power...[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

U.S. Const. Art. I, § 8, cl. 8 (Emphasis Added).

Dr. Tafas has a viable basis to challenge the Revised Rules based on the Patent Clause. that Defendants seem to have misconstrued the import and thrust of Dr. Tafas’ APA claim predicated on the Patent Clause, which is really two-fold.

First, Dr. Tafas is not claiming that the Patent Clause confers any sort of substantive right upon him *per se* as Defendants suggest. Instead, and similar to the petitioners in Eldred v. Ashcroft, 537 U.S. 186, 212 (2003) and Figueroa v. United States, 57 Fed.Cl. 488, 498-99 (2003), Dr. Tafas merely asserts that actions taken by the USPTO, as a body of the Executive Branch, exceed the limitations set forth in the Constitution because under the Patent Clause because only Congress has the power to pass substantive laws setting down the terms and conditions for patent eligibility. This is consistent with a long-standing judicial precedent recognizing that Congress has exclusive authority in this area and that the USPTO may not enact substantive regulations -- no less ones that would conflict with existing statutes enacted by Congress.<sup>16</sup> E.g., In re Hogan, 559 F.2d 595, 604 n. 13 (CCPA 1977) (“[A] limit upon

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<sup>16</sup> The Federal Circuit has rejected the claim that Section 2(b)(2) grants the USPTO the authority to issue substantive rules. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (“As we have previously held, the broadest of the PTO’s rulemaking powers – 35 U.S.C. § 6(a) [now 35 U.S.C. § 2(b)(2)(A)] – authorizes the Commissioner to promulgate regulations *directed only to* ‘the conduct of proceedings in the [PTO]’; it does NOT grant the Commissioner the authority to issue substantive rules.”) (emphasis in original). The Federal Circuit has reaffirmed its confidence in the Merck holding in Eli Lilly & Co. v. Bd. of Regents of University of Washington, 334 F.3d 1264, 1269, n.1 (Fed. Cir. 2003). This holding is bolstered by the fact that Congress has twice tried, and twice failed, to pass legislation that would have expanded the

continuing applications is a matter of policy for Congress, not for us.”); In re Henricksen, 399 F.2d 253 (CCPA 1968) (finding that the USPTO has no statutory basis to limit the number of continuation applications an applicant is allowed if he or she otherwise complies with the requirements of section 120 of the Patent Act).

Second, even assuming arguendo that Congress had validly delegated authority to enact substantive rules to the USPTO (which Congress did not), the USPTO would certainly be subject to the same limitations imposed upon Congress under the Patent Clause in exercising its delegated power. The USPTO’s claim that the Patent Clause is not a limitation on the scope of the Congress’s power is wrong. The Patent Clause places a substantive limitation on Congress’s power, which is qualified authority, “limited to the promotion of advances in the ‘useful arts.’” Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 5 (1966) (the Patent Clause constitutes both a grant of power and a limitation); Eldred, 537 U.S. 186, 212 (2003) ( the primary objective of all acts taken by Congress pursuant to the Patent Clause must be to promote the progress of science and the useful arts (citing Feist Publ’n, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 349 (1991)). Similarly, the Federal Circuit has rejected the argument that the “preamble” of the Patent Clause is not a substantive limit on the power granted to Congress. Figueroa, 57 Fed. Cl. at 499 (interpreting Stiftung v. Renishaw, PLC, 945 F.2d 1173, 1180 (Fed. Cir. 1991)). Likewise, the Patent Clause imposes the same requirement constitutional standard on the USPTO in performing its patent processing role as it does on Congress. A.F. Stoddard & Co., LTD v. Dann, 564 F.2d 556, 564 (D.C. Cir. 1977) (overturning USPTO’s decision to reject an amended continuation application because to do so “would frustrate the constitutional objective”

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USPTO’s rulemaking authority. The Patent Reform Act, H.R. 2795, 109th Cong. (2005); S. 3818, 109th Cong. (2006).

underlying the Patent Clause). The Patent Clause is the very basis on which the USPTO was established. Sperry v. Florida, 373 U.S. 379, 403 (1962).

The Constitution is the supreme law, and, therefore, no regulation established by the USPTO may be inconsistent with it. U.S. Const. art. VI. The Constitution commands that the system Congress establishes must be to ‘promote the Patent of ...useful Arts.’ Graham, 383 U.S. at 5-6. “It is the duty of the Commissioner of Patents...in the administration of the patent system to give effect to the constitutional standard by appropriate application...of the statutory scheme of the Congress.” Id. at 6. Thus, the Patent Clause is an independent factor that the USPTO must “weigh” when establishing regulations under the patent system. Here, the Revised Final Rules are invalid under the APA because they contravene to the primary purpose of the Patent Clause – to promote the progress of the science and the useful arts. As will be established at trial, the Revised Rules not only do not promote this constitutional objective, but in fact retard it, rendering the Revised Rules unconstitutional.

For all the foregoing reasons, Dr. Tafas has stated a claim upon which relief may be granted and Defendants’ motion should be denied.

**B. The Implementation and Retroactive Application of Revised Rules Deprive Dr. Tafas of Property without Due Process of Law.**

Dr. Tafas has stated a viable claim under the APA because the Revised Rules are inconsistent with Article 5 of the United States Constitution, which prohibit the taking of property rights without compensation or due process of law.

First, the Amended Complaint provides a lengthy description of Dr. Tafas’ property interests that are impaired by virtue of the Revised Rules, which allegations are incorporated by reference into the Second Count and plainly satisfy the liberal notice pleading requirements of the Federal Rules of Civil Procedure. (See Amended Complaint, ¶¶ 1-60).

Thus, there is no merit to Defendants' contention that Dr. Tafas has failed to plead his property interest with sufficient particularity to state a claim. (Def. Mem. at pp. 29).

Second, Dr. Tafas respectfully disagrees that that he has no protectible property interest whatsoever in a patent application that he filed in reliance on existing statutory protections, particularly where there has been an waiver of trade secret protections as a result of applying for the patent.<sup>17</sup> The retroactive application of the Revised Rules to his already pending application will deprive Dr. Tafas of his property without adequate due process.<sup>18</sup> The Fifth Amendment commands that “[n]o person shall...be deprived of life, liberty, or property, without the due process of law.” Patents and patent applications are property that is protected by the Due Process Clause of the Fifth Amendment. See 35 U.S.C. §261 (2007) (“patents shall have the attributes of personal property”); Consolidated Fruit-Jar Co. v. Wright, 84 U.S. 92, 96 (1876) (“A patent for an invention is as much property as a patent for land.”); Winchester v. Commissioner, 27 B.T.A. 798, 801 (1933) (“It is now well settled that patent applications are property.”).

In exchange for the public disclosure of ideas and the benefits such disclosure brings to society, the government grants a patentee the right of exclusion in his patent. Kewanee Oil Co. v. Bicron, 416 U.S. 470, 480-81 (1974). In disclosing his ideas, which until disclosed were held as trade secrets (and in which Dr. Tafas maintained a property right), Dr. Tafas relied

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<sup>17</sup> See Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003 (1984) (property rights for Fifth Amendment purposes may exist in intangibles such as trade secrets).

<sup>18</sup> Retroactive application of a regulation should be declared unconstitutional pursuant to the Due Process Clause if, after balancing the considerations on both sides, the Court determines that the regulation is unreasonable. Summit Nursing Home, Inc. v. U.S., 572 F.2d 737 (Ct.Cl. 1978).

upon the exclusivity that results from the quid pro quo bargain by fully disclosing his ideas in his patent application. Now, Dr. Tafas is at risk that he will be unable to fully pursue the full scope of each claim filed in his original parent application.

Based on the statutory protections in effect before the Revised Rules, and as required by the Patent Act, Dr. Tafas fully disclosed his original ideas in his patent applications with the reasonable expectation that he would be afforded the opportunity to file as many continuation applications as might prove necessary to secure patent protection for his work. Here, the retroactive application of the Revised Rules to applications filed before November 1, 2007 effectively denies and/or materially impairs Dr. Tafas' ability to claim priority to all his patentable ideas back to his original filing date. This deprives Dr. Tafas of valuable property rights (both in terms of loss of advantage as to the scope of his patent protection and, at the same time, diminishing his trade secret rights in that Dr. Tafas may not have filed for a patent had it been foreseeable that the Revised Rules would be enacted). Moreover, since the USPTO has no authority to enact substantive rules at all, its promulgation of the Revised Rules and ancillary impairment of the property interests of patent applicants would seem to be almost by very definition "without due process of law."

Finally, Defendants contention that there are no constitutional protection with respect to changes in "procedural" rules presupposes that the Revised Rules are in fact procedural. This is a hotly disputed point of disagreement between parties in that Dr. Tafas contends the Revised Rules are "substantive" -- which would render the cases cited by Defendants on this issue inapposite. For all the foregoing reasons, Defendant's motion to dismiss the Second Count should be denied.

CONCLUSION

WHEREFORE, for all the foregoing reasons, Plaintiff objects to Defendants' Partial Motion to Dismiss dated October 4, 2007 and respectfully moves the Court to deny the motion, and grant any further, different or other relief as the Court deems equitable and proper.

Dated: October 26, 2007

Respectfully submitted,

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