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# **EXHIBIT 7**

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

TRIANTAFYLLOS 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: 1:07-CV-00846-JCC-TRJ

# FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF AND PETITION FOR REVIEW OF RULEMAKING

Pursuant to Fed. R. Civ. P. 15(a), the Plaintiff, Dr. Triantafyllos Tafas ("Plaintiff" or "Dr. Tafas"), brings this Amended Complaint against Defendants Jon W. Dudas, in his official capacity as United States Under-Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office ("USPTO"), and the United States Patent and Trademark Office, through his undersigned counsel, Kelley Drye & Warren LLP, alleging as follows:

### **PARTIES**

Plaintiff Dr. Tafas is an individual residing in Rocky Hill, Connecticut.
 Dr. Tafas is an inventor on U.S. Patent Application Serial No. 11/266948 (the "Tafas Patent")

Application"). Dr. Tafas has filed three (3) continuation-in-part applications of U.S. Patent Application Serial No. 11/266948 on August 10, 2007 and one (1) continuation-in-part application on September 7, 2007. Dr. Tafas' invention pertains to capturing the heat from an automobile's internal combustion engine manifold. Once that heat is captured, it may be utilized in any number of ways to improve the automobile's performance. For example, the proposed concept has the potential to improve fuel consumption by the automobile's engine with a significant effect in the miles-per-gallon performance. Additionally, acceptance of Dr. Tafas' concept by the automotive industry will reduce exhaust gas emission and thus contribute in addressing concerns related to the rise of atmospheric carbon dioxide and global warming. Dr. Tafas discloses multiple devices in which the captured heat may be utilized. Dr. Tafas is also an inventor on more than seventeen (17) patents pending and on eight (8) U.S. issued patents. Lastly, Dr. Tafas qualifies as a "small entity" under 37 C.F.R. § 1.27(a)(1).

- Defendant, the United States Patent and Trademark Office, is an administrative agency of the United States Department of Commerce. The address for the USPTO's headquarters is 600 Dulany Street, Alexandria, Virginia 22314.
- 3. Defendant Jon W. Dudas is the U.S. Under-Secretary of Commerce for Intellectual Property and the Director of the USPTO (the "Director" or "Dudas") and is being sued in his official capacity. The place of business and service address for Dudas is the same as for the USPTO as set forth in paragraph 2 above.

### JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338, inasmuch as this is a civil action arising under the laws and Constitution of the United States, including the laws relating to patents. This Court also has jurisdiction pursuant to 5 U.S.C. § 611 (the Regulatory Flexibility Act's judicial review provisions), 5 U.S.C. §§ 701-706 (the

Administrative Procedure Act's judicial review provisions) and the Declaratory Judgment Act, 28 U.S.C. § 2201.

5. Venue is proper in this District pursuant to 35 U.S.C. § 1(b) and 28 U.S.C. § 1391(e).

### NATURE OF ACTION

- 6. This action is brought for declaratory judgment pursuant to 28 U.S.C. § 2201 et seq., and for judicial review under the Administrative Procedure Act ("APA"), 5 U.S.C. Chapt. 7, and the Regulatory Flexibility Act ("RFA"), 5 U.S.C. § 611. Plaintiff seeks the entry of a judgment, inter alia, to: (1) prevent Defendants from implementing sections 1.75, 1.78, 1.114, 1.265 and 1.704 of certain new federal regulations promulgated by the USPTO, with an effective date of November 1, 2007, which were published at 72 Fed. Reg. 46716, 46835-43 (Aug. 21, 2007) and are to be codified at 37 C.F.R. Part 1 (the "Revised Rules"); (2) have the Revised Rules, in toto, declared null, void and without legal effect, inter alia, as being beyond the rule making power of the USPTO and as inconsistent with various federal statutes and Article I, Section 8, Cl. 8, and the Fifth Amendment to the United States Constitution; and, (3) vacating and remanding the Revised Rules, including requiring Defendants to comply with the requirements of the APA, 5 U.S.C. § 553, and the RFA, 5 U.S.C. § 601 et seq., in promulgating any regulations in the future concerning the subject matter of the Revised Rules.
- 7. As set forth more specifically below, the Revised Rules should be permanently enjoined and declared null and void, among other reasons, because they: (1) violate and conflict, in whole or in part, with Sections 2, 41, 101, 102, 112, 120, 121, 122, 131, 132, 151, 200-203, 251 and 365 of the Patent Act (35 U.S.C. §§ 1 et seq.) and, as such, exceed the USPTO's rule making authority delegated by Congress; (2) violate and conflict with Sections

553(b)-(c) and 706(2) of the APA (5 U.S.C. §§ 553(b)-(c) and 706(2)), among other ways, because the USPTO purported to enact rules with retroactive effect; denied the public of its right to be informed of and meaningfully comment on "the terms or substance of the proposed rule"; by promulgating rules that are arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, contrary to Plaintiff's constitutional rights and in excess of the USPTO's statutory jurisdiction and authority; and (3) violate and conflict with the RFA, 5 U.S.C. §§ 601-612, because the USPTO erroneously certified under RFA Section 605(b) that the Revised Rules would not have a significant impact on a substantial number of small businesses and failed to prepare a Final Regulatory Flexibility Analysis in contravention of RFA Section 604.

### FACTS APPLICABLE TO ALL COUNTS

- A. THE USPTO'S ENACTMENT OF THE REVISED RULES.
- 8. On January 3, 2006, the USPTO published two (2) notices of proposed rule making. The first was titled "Changes to Practice for Continuing Applications, Requests for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" ("Proposed Rule I"). 71 Fed. Reg. 48 (Jan. 3, 2006). The second proposed rule was titled "Changes to Practice for the Examination of Claims in Patent Applications" ("Proposed Rule II"). 71 Fed. Reg. 61 (Jan. 3, 2006).
- 9. Comments on Proposed Rule I were solicited, but the USPTO refused to hold formal public hearings. Upon information and belief, Proposed Rule I received the greatest number of extensively briefed negative comments of any proposed rule package by the USPTO in its history. Proposed Rule II also received a very large number of negative comments.
- 10. In April 2007, it was widely reported that the USPTO was seeking to make final a substantially revised version of Proposed Rules I and II pending approval by the United States Office of Management and Budget. Despite the reported substantial modifications

(which rumor was later substantiated in the final Revised Rules), and public requests for republication of the modified proposed rules, USPTO refused to re-publish or allow comment on the changes to the rules or hold public hearings.

- Moreover, upon information and belief, one or more FOIA requests were 11. filed with the USPTO by a number of interested parties seeking, among other things, information supporting the USPTO's stated basis and rationale supposedly supporting the need for Proposed Rules I and II. However, the USPTO refused to provide the requested information. Upon information and belief, the USPTO may also have non-privileged memoranda questioning the statutory validity of the Revised Rules, in whole or in part.
- On August 21, 2007, the USPTO published a Final Rule in the Federal 12. Register purporting to issue final regulations entitled "Changes to Practice for Continued Examination of Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications." 72 Fed. Reg. at 46716-843. As stated, this rule modifies and amends, among other regulations, 37 C.F.R. 1.75 (hereinafter referred to as "Revised Rule II") and 37 C.F.R. 1.78 (hereinafter referred to as "Revised Rule I"). See id. at 46836-41. Modifications were also made to 37 C.F.R. 1.265, requiring an "examination support document," id. at 46842, and patent term adjustment provisions were set forth in changes to 37 C.F.R. 1.704. Id. at 46843. The Revised Rules have an effective date of November 1, 2007. Id. at 46716-17.
- 13. Revised Rule I requires that a third or subsequent voluntary-divisional application, continuation application or continuation-in-part application, be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted. 72 Fed. Reg. at 46839 (37 C.F.R. § 1.78(d)(1)(vi)). This substantially

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changes prior law which allowed for multiple and unlimited continuing applications without any explanation or showing of good cause. See 35 U.S.C. § 120.

- 14. Pursuant to Revised Rule I, the USPTO may, in the subjective discretion of the Director, deny an applicant the benefit of priority claimed to a prior application in all third or subsequent voluntary-divisional continuation or continuation-in-part applications, regardless of whether the express statutory requirements for filing such continuing application have otherwise been met. 72 Fed. Reg. at 46839 (37 C.F.R. § 1.78(d)(1)(vi)).
- 15. Revised Rule I also requires that patent applicants (or assignees) who file multiple patent applications having the same effective filing date, overlapping disclosure, and a common inventor include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation as to why there are patentably indistinct claims in multiple applications. 72 Fed. Reg. at 46840 (37 C.F.R. § 1.78(f)).
- 16. Revised Rule I will retroactively effect patent applications filed before its effective date. First, an applicant will only be allowed two (2) voluntary-divisional continuations or continuation-in-part applications (or one of each) after the effective date of Revised Rule I, unless the applicant meets the new requirements. 72 Fed. Reg. at 46838-39 (37 C.F.R. § 1.78(d)). If the applicant has already filed two (2) or more voluntary-divisional continuations, or two (2) or more continuation-in-part applications, or both a voluntary-divisional continuation and a continuation-in-part application prior to the Revised Rules' publication date, the applicant is entitled to file only one other without petition. 72 Fed. Reg. at 46840 (37 C.F.R. § 1.78(d)(1)).
- 17. In addition, Revised Rule I creates the presumption that inventions are patentably indistinct if a patent applicant files multiple applications with the USPTO with the same filing date, or within two (2) months of such date, and the applications include common

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inventors and overlapping disclosures. 72 Fed. Reg. at 46840 (37 C.F.R. § 1.78(f)(2)(i)).

- 18. Revised Rule I requires that the applicant rebut the presumption with an explanation as to why the claims in the application are distinct or, alternatively, submit a terminal disclaimer and explain to the subjective satisfaction of the USPTO good cause as to why two (2) or more pending applications should be maintained. 72 Fed. Reg. at 46840 (37 C.F.R. § 1.78(f)(2)(ii)).
- 19. Revised Rule II requires that if an application contains more than a specified number of independent claims (five (5)) or, if the applicant wishes to have initial examination of more than a specified number of total claims (twenty-five (25)), then the applicant must provide an examination support document that covers all of the claims under revised 37 C.F.R. § 1.265. 72 Fed. Reg. at 46842 (37 C.F.R. § 1.265). Such examination support document is onerous, and will require significant monetary outlays to prepare.
- 20. Revised 37 C.F.R. § 1.704 allows the USPTO to reduce patent term if an application contains more than five (5) independent or twenty-five (25) total claims and did not have an examination support document filed until after four months from the filing date of the application, or if an amendment in a application in which an examination support document was not filed before the first office action on the merits, resulted in the application containing more than 5/25 claims. 72 Fed. Reg. at 46843 (37 C.F.R. § 1.704).
  - B. DR. TAFAS HAS BEEN INJURED AS A RESULT OF THE ENACTMENT OF THE REVISED RULES.
- 21. Under the law as it existed for over 100 years prior to the USPTO's promulgation of the Revised Rules, an inventor was entitled to file an application to patent his original ideas and, if at some future time the inventor discovered other patentable claims arising from his original application, the inventor could file an application for a continuation or

"voluntary-divisional" application to patent those claims as well. There was no limit to the number of such continuing applications an inventor could file prior to the promulgation of the Revised Rules.

- 22. The right to freely file multiple continuing applications is extremely valuable to an inventor like Dr. Tafas, *inter alia*, because the continuing application is deemed to relate back to the date of the inventor's original application. Thus, the filing of a continuation provides an inventor with a priority right against all others concerning patented claims stemming from the inventor's original continuing application.
- 23. Furthermore, prior to the Revised Rules there were no USPTO restrictions on the number of independent and total claims inventors were allowed to claim in a patent application, subject only to the need to pay certain statutorily mandated fees for asserting such claims. The unfettered right to determine the number of claims that need to be filed with the USPTO in order to adequately protect an invention is extremely important to inventors.
- 24. Here, the Revised Rules substantially impair the rights of patent applicants, such as Dr. Tafas, provided under the Patent Act of 1952, 35 U.S.C. §§ 1 et seq., as amended (the "Patent Act") by, among other things, significantly reducing the chances that they will be successful in obtaining a patent, eroding the confidentiality protections afforded by the Act, making it more likely that patentable inventions will be improperly copied or used by others, and by foisting unreasonable and largely unacknowledged (i.e., vastly understated) costs on small entity inventors like Dr. Tafas.
- 25. For example, under both the Patent Act and the USPTO's continuation related regulations applicable before the promulgation of the Revised Rules, Dr. Tafas was permitted to file an unlimited number of continuation applications ("continuations"), voluntary-

divisional applications and continuation-in-part applications. Each of such continuing applications was deemed to relate back to the filing of the original patent application. Now, the USPTO purports to strip inventors like Dr. Tafas of their previously existing right to file an unlimited number of such continuing applications under the Revised Rules.

- 26. Under prior law Dr. Tafas and other similarly situated inventors were able to claim their new inventions without the need to file an expensive examination support document. The Revised Rules, however, require inventors to file exceedingly costly examination support documents under certain circumstances (explained in greater detail below), while effectively denying patent applicants such as Dr. Tafas their statutorily provided right to make such unlimited filings.
- 27. The Revised Rules also adversely impact patent applicants who have filed or may file multiple: (i) voluntary-divisional applications (seeking differing inventions from those sought in an initial application); (ii) involuntary-divisional applications (i.e., claims subject to a restriction requirement claiming subject matter previously disclosed but not claimed in the parent application); (iii) continuation-in-part applications; or, (iv) requests for continuation examination ("RCE"). See 72 Fed. Reg. at 46837 (37 Fed. Reg. § 1.78(a)(Definitions) and 72 Fed. Reg. 46841 (37 C.F.R. § 1.114) (RCE Requirements).
- 28. Dr. Tafas and other persons or entities with pending patent applications are also injured by the Revised Rules' new requirements, which are applicable to those applicants who file any third or subsequent continuing application after November 1, 2007, or who file any subsequent continuation application after the filing of a continuation application relating to a patent application pending on August 21, 2007. The reason for this is that under the Revised Rules they will now be required to make "a showing [to the USPTO] that the

amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application." 72 Fed. Reg. at 46838-39 (37 C.F.R. § 1.78(d)). Similar requirements apply to filings of requests for continued examination of an application. 72. Fed. Reg. at 46841 (37 Fed. Reg. § 1.114).

- 29. Further, under the Revised Rules involuntary-divisional claims may be limited to only those claims that existed in the previous patent application due to the USPTO's new definition of "divisional application." 72 Fed. Reg. at 46837 (37 C.F.R. § 1.78(a)(2)). No provision is made for adding of right new claims to, and/or amending existing claims, to cover previously disclosed, but not expressly claimed, subject matter.
- 30. The Revised Rules also adversely impact patent applicants, inter alia, by limiting the number of claims in an application for which an examination support document was not filed before the first office action on the merits, regardless of whether the application was filed before or after the Revised Rules' effective date of November 1, 2007. 72 Fed. Reg. at 46836-37 (37 C.F.R. 1.75(b)). An inventor filing an initial patent application that contains more than five (5) independent claims or twenty-five (25) total claims must file a burdensome and extremely costly "examination support document." 72 Fed. Reg. at 46836 (37 C.F.R. § 1.75(b)(1)). This rule applies equally to applications filed prior to the announcement of this rule, as to future applications, unless "a first [USPTO] action on the merits was mailed before November 1, 2007." 72 Fed. Reg. at 46826.
- Moreover, the USPTO failed to publish this so-called "5/25 Rule" for 31. comment as part of its rule making process for the Revised Rules thus depriving Dr. Tafas and other interested persons an opportunity to provide comment on its adverse effects.

- 32. The Revised Rules concerning voluntary-divisional applications, continuation applications, and continuation-in-part applications substantially and adversely change Dr. Tafas' rights concerning the filing of future continuing applications and adversely impair his ability to patent inventions that flow from his original invention. As such, the Revised Rules create a disincentive for inventors like Dr. Tafas to continue inventing, among other reasons, because there is a very real possibility that he will not be able to realize the full economic benefit of his work. These Revised Rules also create a disincentive for inventors like Dr. Tafas to reveal the full scope of their work in a patent application because there is a high likelihood that their disclosed work and research could be cannibalized by others to their own economic benefit.
- 33. Upon information and belief, the Revised Rules will decrease Dr. Tafas' ability to raise funds for the development of products that stem from his applications. Further, a higher portion of the raised funds will have to be spent towards securing intellectual property rights. See 72 Fed. Reg. at 46775 (USPTO stated that lack of funds would be an insufficient cause for it to grant a petition to file further voluntary-divisional continuations).
- 34. In short, the Revised Rules substantially change the regulatory landscape for obtaining patents under which inventors like Dr. Tafas have traditionally operated and, if not enjoined and/or declared invalid, will frustrate and undermine the purposes of the U.S. patent laws by, inter alia, preventing Dr. Tafas and other similarly situated inventors from realizing the full economic potential of their work.

### FIRST COUNT

### (THE REVISED RULES ARE CONTRARY TO THE PATENT ACT AND APA)

35. Dr. Tafas realleges and incorporates by reference the allegations of paragraphs 1-34 as fully as if set forth at length herein.

- 36. The Patent Act established the USPTO, which is responsible for, *inter* alia, the granting and issuing of patents and for disseminating information to the public with respect to patents. 35 U.S.C. Chapt. 1. The USPTO Director (i.e, Defendant Jon Dudas) administers the issuance of patents. Id. § 3.
- 37. Section 2 of the Patent Act authorizes the Director to establish regulations that facilitate and expedite the processing of patents, but limits the Director's power to enacting regulations that are not inconsistent with the law. Id. § 2(C).
- 38. Section 41 of the Patent Act sets forth Congressionally-mandated fees in respect of patent applications filings. Id. § 41. Among its provisions is a statutorily set fee to be charged for filing in excess of twenty (20) total claims and three (3) independent claims, as well as a specific fee for filing a multiple dependent claim. Id. There is no provision in the Patent Act that authorizes the Director to change the amount of these fees without statutory authorization.
- 39, Section 101 of the Patent Act permits an applicant to obtain a patent on any new and useful improvement on an invented or discovered "new and useful process, machine, manufacture, or composition of matter," subject to meeting the requirements of the Patent Act. Id. § 101. No limitation is made on the right to seek a patent on any new and useful improvement of a previously applied for invention.
- 40. Sections 101 and 102 of the Patent Act require the USPTO to issue a patent to the first inventor of subject matter patentable under the Patent Act. No provision is made for the USPTO to deny a first inventor a patent on an patentable invention based on, among other things, a failure of the inventor to incorporate such invention into the confines of a filed claim within two (2) continuation applications of the parent application. It further does not

limit the claims to those claims that were subject to the restriction requirement ("a patent issued on application" but not on the original form).

- 41. Section 112 of the Patent Act, in part, defines what is meant in the Act by the terms "dependent claim," and "multiple dependent claim." Id. § 112. No provision is made for the Director to alter these statutory definitions created by Congress.
- 42. Section 120 grants a patent applicant the benefit of an earlier filing date of a previous application which is filed by an inventor or inventors named in the previous application if such application is filed before the patenting or abandonment or termination of proceedings on the first application. Id. § 120. No provision is made for limiting an applicant's right to claim benefit of an earlier filing date of a previous application.
- 43. Section 121 defines what is meant in the Patent Act by the term "divisional application." Id. § 121. By implication, by authorizing the Director to dispense with formalities in those divisional applications "directed solely to subject matter described and claimed in the original application as filed," the statute recognizes that the term "divisional application" includes situations wherein the divisional application is not "directed solely to subject matter described and claimed in the original application as filed." Id.
- 44. Further, Section 121 provides a special benefit for involuntary divisions by providing that "[a] patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such requirement, shall not be used as a reference either in the [USPTO] or in the Courts against . . . the original application . . . . " Id. This indicates, therefore, that a divisional application need not be due to a restriction requirement. A divisional application might have additional claims

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directed to subject matter described but not claimed in the original application. In short, Section 12 allows this right to file a divisional whether or not the first application was or was not subject to a restriction requirement with respect to the claims pursuant to a USPTO office action. Id. No provision is made for the USPTO to change the definition of a "divisional application," nor to limit its application only to those applications "directed solely to subject matter described and contained in the original application as filed," as in so-called "voluntary divisionals."

- 45. Sections 120 and 121, when applied together, also permit a hybrid form of application which is, in effect, if not in name, both a divisional application and a continuation-inpart application. No provision is made within either of the above statutory sections for the USPTO to prohibit a hybrid continuation-in-part/divisional application, which discloses additional matter not disclosed in the original application but includes claims to subject matter that was disclosed in the original application and optionally the new subject matter.
- 46. Section 122 requires the USPTO to keep applications for patents in confidence with "no information concerning the same given without the authority of the applicant or owner unless necessary to carry out the provisions of any Act of Congress or in such special circumstances may be determined by the Director." Id. § 122 (emphasis added). Other than for allowing publication of the application within 18 months if the applicant has not sought a waiver by agreeing not to file internationally, and wherein special circumstances lie with a particular patent application, the Patent Act does not authorize or allow the USPTO to publicly disclose any information pertaining to such applications.
- 47. Section 131 requires that the Director cause an examination of all the alleged new inventions in a patent application, and requires the Director to issue a patent if upon such examination "it appears that the applicant is entitled to a patent under the law." Id. § 121.

No provision is made for the Director to deny a patent on a claim asserting a new invention solely due to the patent application having more than any specified number of claims.

- 48. Section 132 requires the Director "to provide for the continued examination of applications for patent" and to establish appropriate fees for the continued examination of applications. Id. § 132(b). Section 132 does not empower the Director to deny a continued examination of an application and/or to promulgate regulations having the practical effect of denying an applicant a continued examination of an application.
- Section 151 requires that a notice of allowance of an application be given 49. if "it appears that the applicant is entitled to a patent under the law." Id. §151. No provision is made for the Director to deny a notice of allowance on an claim asserting a new invention solely due to the patent application having filed more than a specified number of claims.
- 50. Section 251 allows for reissue of defective patents and in conjunction with Section 121 also provides for divisional applications in the reissue application. Id. § 251. No statutory provision is made for the USPTO to unilaterally remove an applicant's right to file a divisional application in a reissue application.
- Section 200 sets forth congressional policies and objectives including to 51. promote the use of the patent system to advance the utilization of inventions arising from federally supported research or development. Id. § 200. Further, Section 201 indicates that such promotion relates both to inventions and discoveries which are or "may be" patentable. Id. §201.
- 52. Section 203 grants a Federal Agency providing the federal funds "marchin rights" to require a contractor to grant a non-exclusive, partially exclusive, or exclusive license in the subject invention to a "responsible applicant or applicants" in any field of use. Id. § 203. No provision is made for the USPTO to ignore such express statutory policies and objectives in connection with the USPTO's rule making, including by limiting the "march-in rights" provided

to applicants under Section 203 by limiting the number of claims that a contractor may obtain with respect to different fields of use of an application.

- 53. Section 365 grants, in part, benefit of the filing date of a prior application based on a prior filed international application which designates the United States and provides. inter alia, that "an international application designating the United States shall be entitled to the benefit of the filing date of a prior national application or a prior international application designating the United States" if such is in accord with the conditions and requirements of Section 120 of the Patent Act. Id. § 365(c) (emphasis added). No provision is made for the USPTO to deny a claim in a divisional application due to more than one (1) priority claim having been made previously.
- 54. The APA prohibits agency action which is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Furthermore, the APA prohibits agency action which is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." Id. § (C). APA Section 702 provides a party "suffering legal wrong because of agency action," such as Dr. Tafas, with the right of judicial review. Id. § 702.
- 55. Here, Defendants exceeded the scope of their statutory authority, abused their discretion, and acted arbitrarily and capriciously by enacting Revised Rules that are, inter alia, contrary to 35 U.S.C §§ 2, 41, 101, 102, 112, 120-122, 131, 132, 151, 251, 200-203, and 365.
- 56. The Revised Rules promulgated by the USPTO illegally eviscerate or otherwise alter the above referenced statutory rights and protections provided for by Congress, in

derogation of the USPTO's limited rulemaking powers under 35 U.S.C. § 2, in several important ways including, but not limited to, the following:

- In overriding the Congressional definition of "dependent" claim and (a) "multiple dependent" claim in Section 112(4)-(5) of the Patent Act, and by
- purporting to impose new fees. This is contrary to 35 U.S.C. § 41(a)(1)(B). Revised Rule 1.75(b)(2) engrafts a further limitation on the definition of a dependent claim in stating that "[a] claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes ... and for purposes of ... this section." Similarly, Revised Rule 37 C.F.R. § 1.75(b)(4) engrafts a further limitation on the definition of "multiple dependent claim" in causing the same to be considered to be that number of claims to which direct reference is made therein.
- (b) In limiting the ability of an applicant to seek protection on "new and useful improvements" to a "new and useful process, machine, manufacture or composition of matter" for which a patent application has already been made as permitted by 35 U.S.C. §101, by limiting continuation-in-part applications off of divisional applications pursuant to Revised Rule 37 C.F.R. § 1.78(d)(1)(iii).
- (c) In limiting the right of a first inventor to obtain a patent on a new invention that is patentable under the Patent Act as provided by 35 U.S.C. §§ 101 and 102, as provided by 37 C.F.R. § 1.78(d)(1)(i) which limits continuation filings to two applications.
- (d) In prohibiting an applicant from seeking -- as of right -- the benefit of an earlier filing date of a previous application which was filed by an inventor or inventors named in the previous application, as is expressly sanctioned by 35 U.S.C. § 120, and by limiting the number of continuation applications and continuation-in-part applications, separately or in conjunction, to two (2) filings without the need to provide a petition and showing to the office (Revised Rule 37 C.F.R. § 1.78(d)(1)(i)). Due to the problems, delineated below, associated with the requirements of an examination support document as set forth at 37 C.F.R. § 1.265, the USPTO's petition process makes the right to file further continuations after petition illusory.
- In prohibiting under Revised Rule 37 C.F.R. § 1.78(d)(1)(ii) an applicant (e) from filing voluntary divisionals, as allowed for under Section 121. See 35 U.S.C. § 121 (implicitly recognized in the statute as set forth *supra*).
- (f) In prohibiting under Revised Rule 37 C.F.R. § 1.78(d), an applicant from filing an involuntary divisional with additional claims beyond those originally existing in the parent application or, once filed, amending the claim, so as to include disclosed but not claimed subject matter, as allowed for under section 121.

- (g) In prohibiting under Revised Rule 37 C.F.R. § 1.78(d)(i)(ii) and (iii) the filing of a continuation-in-part/divisional application hybrid as permitted under 35 U.S.C. §§ 120, 121.
- (h) In requiring applicants to identify, by a series code and serial number, each other commonly owned non-provisional applications filed within two months of the claimed filing or priority date of the application, 72 Fed. Reg. at 46840 (37 C.F.R. § 1.78(f)(1)(i)), and requiring an applicant to file papers to eliminate patentably indistinct claims from all but one application and to argue against any examiner-required elimination of patentably indistinct claims in a response to an office action, without making provision to keep such serial code information and patentably indistinct claim arguments confidential, in contravention of 35 U.S.C. § 122. See 35 U.S.C. § 122 (requiring that applications for patents be kept in confidence by the USPTO with "no information concerning the same given without the authority of the applicant or owner") (emphasis added).
- (i) In requiring an applicant to cancel allowable claims in an amendment, in an application that was not filed with a compliant examination support document (Revised Rule 37 C.F.R. § 1.265) before the first office action on the merits, (or alternatively having the amendment treated as non-responsive and having the application go abandoned), when such amendment results in an application having claims exceeding the 5/25 threshold limitation (Revised Rule 37 C.F.R. § 1.75(b)), in derogation of 35 U.S.C. § 131, which requires that the Director issue a patent if upon examintation "it appears that the applicant is entitled to a patent under the law," and 35 U.S.C. §151, which requires the USPTO to issue a notice of allowance to an applicant if an "applicant is entitled to a patent under the laws."
- (j) In restricting the right to file a request for continued examination ("RCE") to one RCE (Revised Rule 37 C.F.R. § 1.114(f)), in derogation of Patent Act Section 132(b) which states that the "Director <u>shall</u> prescribe regulations to provide for the continued examination of applications for patent <u>at the request of the applicant</u>." 35 U.S.C. § 132(b) (emphasis added).
- (k) In redefining a "continuing application," "divisional application," "continuation application," and "continuation-in-part application," (72 Fed. Reg. at 46837 (37 C.F.R. 1.78(a)), contrary to 35 U.S.C. §§ 120, 121 and 251. For example, 35 U.S.C. § 251 in conjunction with 35 U.S.C. § 121 allows for the filing of divisional applications in a reissue application. The new definition of "divisional application" under the Revised Rules defines a divisional application as a "continuing application" which claims benefit under 35 U.S.C. §§ 120, 121, or 365(c). No provision is made for a divisional under 35 U.S.C. § 251.

- In failing to take into account in the promulgation of the Revised Rules the policy and objective of Congress with respect to federally supported research or development in the terms of the promotion of the utilization of inventions, that are or "may be" patentable (35 U.S.C. § 201), and, specifically, in requiring that a contractor-applicant conduct prosecution of a generic claim in an initial application and its continuation or continuation-in-part application to the exhaustion of any appeals on any generic claim, (Revised Rule 37 C.F.R. § 1.78(d)), before a contractor-applicant may file a divisional application to any non-elected species, even if after filing the generic claim, it is determined by a contractor-applicant receiving federal grants that a particular species is desired to be immediately commercialized. Delays in commercialization of products may also be introduced when an interference proceeding is sought in a second continuation application in conjunction with new claims to the anticipated commercial product, and when a USPTO restriction requirement requires traverse, thus delaying the filing of claims to an anticipated commercial product in an involuntary divisional pursuant to 37 C.F.R. § 1.78(d).
- (m) In failing to take into account the effect of the Revised Rules on the "march-in rights" granted to Federal Agencies providing federal funds for research and development pursuant to 35 U.S.C. § 203.
- (n) In failing to allow an applicant to claim priority to a divisional application from which priority has already been claimed in an international application designating the United States when such claim is in accord with the conditions and requirements under 35 U.S.C. § 120 (Revised Rule § 1.78(d)(iv)(C)), in derogation of 35 U.S.C. § 365.
- 57. As a result, the Revised Rules are both *ultra vires* and arbitrary, capricious, an abuse of discretion, not in accordance with law, and in excess of the USPTO's statutory jurisdiction and authority, in violation of 5 U.S.C. § 706(2).

### SECOND COUNT

# (THE REVISED RULES ARE CONTRARY TO THE UNITED STATES CONSTITUTION AND THE APA)

- 58. Dr. Tafas realleges and incorporates by reference the allegations of paragraphs 1-57 as fully as if set forth at length herein.
- 59. The APA prohibits agency action which is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B). APA Section 702 provides a party

"suffering legal wrong because of agency action," such as Dr. Tafas, with the right of judicial review. <u>Id.</u> § 702.

- 60. The Director's and USPTO's actions in promulgating the Revised Rules are violative of Article I, Section 8, Cl. 8 of the United States Constitution by virtue of the USPTO, upon information and belief, failing to appropriately weigh the effect of its regulations on the promotion of the progress of science and the useful arts.
- 61. The Director's and USPTO's actions in promulgating the Revised rules are violative of the Fifth Amendment to the Constitution in effectuating a deprivation of property without due process of law.

#### THIRD COUNT

### (VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT)

- 62. Dr. Tafas realleges and incorporates by reference the allegations of paragraphs 1-61 as fully as if set forth at length herein.
- 63. The APA defines "rule" as meaning "the whole or a part of an agency statement of general or particular applicability <u>and future</u> effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency…" 5 U.S.C. § 551(4) (emphasis added).
- 64. Here, the Revised Rules are within the scope of APA Section 551(4) because, among other reasons,
  - (a) the Revised Rules amend currently existing regulations and constitute legally binding requirements;
  - (b) the Revised Rules impose obligations and produce significant impacts on persons seeking approval of patents; and
  - (c) short of undertaking a new rulemaking, the USPTO has no authority to ignore or waive these requirements depending on individual circumstances.

- 65. As part of the initiation of a rulemaking process such as the one at issue, agencies, including the USPTO, must publish a "[g]eneral notice of proposed rulemaking" that, among other things, shall include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." Id. § 553(b)(3).
- 66. "After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Id. § (c).
- 67. As a federal administrative agency, the USPTO is bound to comply with the rule making procedures set forth in Section 553 of the APA. See 35 U.S.C. § 2(b)(2)(B).
- 68. Revised Rule II has an illegally retroactive effect because the USPTO has indicated that it will make the limitation of five (5) independent claims and twenty-five (25) total claims "applicable to any non-provisional application filed before November 1, 2007, in which a first Office action on the merits was not mailed before November 1, 2007." 72 Fed. Reg. at 46716. As a result, this limitation will be applied to already filed patent applications, even though the public was unaware of the new limitation at the time applications were filed.
- 69. The APA also requires an agency such as the USPTO to adhere to certain procedural standards when undertaking a rulemaking like the Revised Rules at issue. Among other things, the agency must publish a notice of proposed rulemaking that apprises the public of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The APA also provides the public the right to comment on any such proposed rules. Id. § 553(c).
- 70. The USPTO has failed to meet its obligations under the APA by, without limitation, adding substantive new regulations to the final rule (i.e., the Revised Rules) that were

not noticed in the proposed rule and which provided the public had no opportunity to comment upon, in violation of 5 U.S.C. § 553(b)(3), (c).

- 71. Provisions existing in the Revised Rules which were not noticed in the proposed rules (and therefore were not subject to the required notice and comment) include, without limitation:
  - (a) the 5 independent claim/25 total claim limitation ("5/25 threshold limitation") before which an examination support document is needed (37 C.F.R. § 1.75(b));
  - (b) the 15/75 claim threshold among all continuing applications in a patent family before which an examination support document needs to be filed (37 C.F.R. § 1.75(b));
  - (c) allowing for serial filed divisionals (as a divisional is redefined by the USPTO 37 C.F.R. § 1.78(d)) in conjunction with the 5/25 threshold limitation, in particular as such regulations cause indistinct claims between applications (making each application being treated as having the total number of claims present in all of the applications pursuant to 37 C.F.R. § 1.75(b)(4)) if the parent application is about to issue, and the applicant desires to maintain the right to maintain further divisionals in the future;
  - (d) treating each application having at least one (1) patentably indistinct claim between them as having the summation of the all of the claims present in each application for purposes of determining whether each application exceeds the 5/25 threshold limitation for an examination support document;
  - (e) the prohibition of filing a continuation-in-part application off of a divisional application (37 C.F.R. § 1.78(d)(1)(iii));
  - (f) a penalty for filing a demand in an international application designating the United States whereby the filing of the demand may preclude filing of a non-provisional application seeking the benefit of the filing date of the international application under 35 U.S.C. §§ 120, 121 and 365 (37 C.F.R. § 1.78(d)(1)(iv));
  - (g) expanding the pre-examination search requirement from each limitation in designated dependent claims to all dependent claims pending in the application if the 5/25 threshold limitation is exceeded (37 C.F.R. § 1.265(a)(1)(b);

- (h) allowing for patent term adjustment if an application contains more than 5/25 claims and no examination support document, and the applicant did not file an examination support document until after four months from the filing date of the application (37 C.F.R. § 1.704); and
- (i) adding a requirement under 37 C.F.R. § 1.265(a)(4) that an applicant must explain in an examination support document why a person of ordinary skill in the art would not have combined the references to arrive at the claimed subject matter (as opposed to the proposed rule that merely stated the applicant would need to argue patentability).
- 72. One or more, or all, of the provisions set forth immediately above are substantive in nature.
- 73. Accordingly, the Revised Rules violate the APA (5 U.S.C. §§ 551(4), 553(b)-(c) and 706(2)) because, among other things, they:
  - A. purport to and do, in fact, have retroactive effect;
  - B. were promulgated without adherence to procedure required by law;
  - C. denied the public the right to provide informed and meaningful comment due to the fact that the subjects addressed in the final rule were not presented to the public for comment in the proposed rule, and the final rule differed materially from the proposed rule more generally.

#### **FOURTH COUNT**

### (VIOLATION OF THE REGULATORY FLEXIBILITY ACT)

- 74. Dr. Tafas realleges and incorporates by reference the allegations of paragraphs 1-73 as fully as it set forth at length herein.
- 75. Plaintiff is a "small entity" as that term is employed in the RFA's judicial review provisions, 5 U.S.C. § 611(a)(1), and as defined by the USPTO. 37 C.F.R. § 1.27(a)(1).
- 76. Under conditions such as this, where an agency is required to promulgate rules in accordance with Section 553 of the APA, the RFA provides that "the agency shall prepare and make available for public comment an initial regulatory flexibility analysis" in

connection with issuing a proposed rule. 5 U.S.C. § 603(a).

- 77. Further, the RFA requires government agencies such as the USPTO to prepare a final regulatory flexibility analysis at the time when final rules (such as the Revised Rules here) are published. Id. § 604. Each final regulatory flexibility analysis is required to contain:
  - (1)a succinct statement of the need for, and objectives of, the
  - (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
  - a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
  - a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
  - a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

5 U.S.C. § 604(a).

78. The only exception to this requirement is "if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." Id. § 605(b). Such certification must, however, be rationally based, inter alia, on an accurate accounting of the underlying regulations' actual

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economic impacts on small entities.

- 79. The RFA's judicial review provisions, at 5 U.S.C. § 611(a)(1)-(2), allow small businesses and small governmental jurisdictions to seek judicial review of, *inter alia*, an agency's failure to develop and prepare a final regulatory flexibility analysis ("FRFA"), as required by 5 U.S.C. § 604; as well as faulty certifications by an agency "that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities" under 5 U.S.C. § 605(b).
- 80. The USPTO unlawfully concluded and certified that the Revised Rules would not have a "significant economic effect on a substantial number of small businesses." 72 Fed. Reg. at 46830-31. As a result of this irrational and unsupported determination, the agency failed to prepare a FRFA.
- 81. In promulgating the Revised Rules, the USPTO violated Sections 604 and 605(b) of the RFA by failing, *inter alia*, to develop a FRFA and by unlawfully certifying that the Revised Rules would not have a significant economic impact on a substantial number of small businesses.
- USPTO downplayed, among other things, the costs of its eleventh hour addition of rules limiting inventors to five (5) independent claims and twenty-five (25) total claims, or in the alternative filing an examination support document; ignored the practical impediments that the limitation on the number of continuing applications and the number of claims that may be made in an application will have on an inventors' ability to vigorously defend patents; and failed to adequately account for the universe of effected small entities.

#### 83. Given the:

(a) significant costs for filing initially filing an examination support document (as set forth by numerous commentators to the proposed regulations) and those

costs attendant to the requirement that each limitation of the claims be searched in respect of all U.S. patents and publications, foreign patents and publications and all non-patent literature (Revised Rule 37 C.F.R. § 1.265(a)(1) and (b));

- (b) prosecution history estoppel issues pertaining to characterizing a reference and setting forth a detailed explanation of patentability in an examination support document (Revised Rule 37 C.F.R. § 1.265);
- (c) costs and difficulty in demonstrating where each limitation of the claims finds support in the written specification (37 C.F.R. § 1.265(a)(5));
- (d) fact that an examination support document provides a road map for litigators seeking to allege inequitable conduct in requiring the applicant to disclose his entire search logic; and
- (e) need for an applicant to file a supplemental examination support document each time an amendment is made to the claims (37 C.F.R. § 1.265(d)), the USPTO knew and understood that an applicant, particularly a small business, would eschew using the examination support document. Upon information and belief, the USPTO understood that the examination support document would act as an insurmountable barrier to small entities and effectively reduces the number of claims that a small entity could file to protect its inventions to 5 independent claims and 25 total claims.
- basis, when it, among other things, ignored its own studies and other studies showing "that many commercially valuable patents are the result of a continuing application, or of a second or subsequent continuing application," 72 Fed. Reg. at 46831, as well as disregarded scores of comments in opposition to the proposed Revised Rules submitted to the USPTO by numerous persons and entities, thus further closing its eyes to the impacts of the Revised Rules on small entity inventors.
- 85. The USPTO also conducted flawed statistical analysis in making its certification that a substantial number of small entities would not be significantly impacted.
- 86. In point of fact, the Revised Rules will have a significant, unraveling economic impact on small entity inventors, including Dr. Tafas, and the USPTO's failure to adhere to Sections 603 and 604 of the RFA (5 U.S.C. §§ 603-604) based on a faulty and

conclusory certification of no significant economic impact pursuant to 5 U.S.C. § 605(b) has caused Dr. Tafas harm.

### PRAYER FOR RELIEF

WHEREFORE, Plaintiff Dr. Tafas requests entry of judgment against Defendants as follows:

- 1. Preliminarily and permanently enjoining the Revised Rules;
- 2. Ordering the Defendant to rescind and otherwise nullify regulations implementing Revised Rules that were not promulgated according to law;
- 3. Declaring, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the Revised Rules were promulgated in violation of the United States Constitution, Patent Act, APA, and RFA for, among others, the reasons stated above;
- 4. Awarding Dr. Tafas costs and attorneys fees incurred in connection with this action pursuant to 28 U.S.C. §§ 1920 and 2412(a)(1)-(b) and (d)(1)(A) and the Equal Access to Justice Act (5 U.S.C. § 504; 28 U.S.C. § 2412);
- 5. Deferring, pursuant to 5 U.S.C. § 611(a)(4)(B), application of the measures contained in the Revised Rules as against small entities until a legally compliant RFA analysis is prepared; and
- 6. Such other relief as is just and proper.

Respectfully submitted,

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Dated: September 7, 2007

## **CERTIFICATION OF SERVICE**

The undersigned hereby certifies that on this 7<sup>th</sup> day of September, 2007, he caused to be served true and correct copies of the foregoing with the Clerk of the Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

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