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

TRIANTAFYLLOS TAFAS,

Plaintiff,

v.

JON 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

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

PRELIMINARY STATEMENT

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiff Dr. Triantafyllos Tafas ("Plaintiff" or "Dr. Tafas") respectfully submits this memorandum of law in support of his motion for a preliminary injunction.

On August 21, 2007, the Defendants, the United States Patent and Trademark Office (the "USPTO"), an administrative agency that is part of the United States Department of Commerce, and Jon Dudas ("Dudas"), in his official capacity as United States Under-Secretary of Commerce for Intellectual Property and Director of the USPTO ("Director") (collectively the "Defendants"), published certain new regulations at 72 Fed. Reg. No. 161 entitled "Changes to Practice for Continued Examination of Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule."

Defendants exceeded their Congressionally delegated authority and violated provisions of the U.S. Constitution by enacting Section 1.75 (37 C.F.R. § 1.75 and hereinafter referred to as "Revised Rule II") and Section 1.78 (hereinafter referred to as "Revised Rule I") (sometimes referred to collectively as the "Revised Rules"). In this action, Plaintiff seeks a declaratory judgment that the Revised Rules are null and void, along with a preliminary and permanent injunction prohibiting the USPTO from putting the Revised Rules into effect, because they are inconsistent with the United States Constitution and other federal law including, without limitation, the following:

> (1) the Patent Act (35 U.S.C. §§ 2, 120, 132 and 365), inasmuch as they exceed the rule making authority delegated to the Defendants by Congress and are contrary to statute; and,
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> (2) the Administrative Procedure Act, 5 U.S.C. §§ 553(c) and 706(2), inter alia, because the USPTO failed to consider all relevant matter presented during the rule-making process and promulgated rules that are arbitrary, capricious, an abuse of discretion, not in accordance with law, in excess of the USPTO's statutory jurisdiction and authority, and contrary to the U.S. Constitution; and,
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> (3) the United States Constitution, Article I, Section 8, Cl. 8 by failing to take in consideration in its rule-making the promotion of "the progress of science and useful arts;" and the Fifth Amendment to the United States Constitution, which prohibits the federal government from taking property without due process of law.

RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff Dr. Tafas is an individual inventor on Patent Application Serial Nos. 11/266,948, 11/837,066, 11/837,075, and 11/837,085 (the "Tafas Patent Applications"). (See Declaration of Dr. Triantafyllos Tafas dated August 21, 2007 at ¶ 3) (hereinafter the "Tafas Decl.," a copy of which is being simultaneously filed herewith). In 1991, Dr. Tafas received a PhD. in Biological Sciences from the University of Athens in Greece. (Id., at ¶ 4.) He authored

his first patent that same year. (Id., at ¶ 4.) He dedicated his research to microscopy, leading him to start a company in 1999 named Ikonisys, Inc. headquartered in New Haven, Connecticut (the "Company"). (Id., at ¶¶ 6-8)

During the next several years, Dr. Tafas traveled back and forth to the United States, while serving as a Visiting Professor at the University of Connecticut and seeking to raise venture capital to continue his microscopy research. (Tafas Decl., at ¶ 6.) After Dr. Tafas personally invested a great deal of time and money in Ikonisys, the Company started to flourish as a result of promising research. (Id., at ¶ 13.) It is believed that the Ikonisys automated microscope will enable the diagnosis of conditions more rapidly than conventional microscopy and could change the world of cancer research and therapies. (Id., at ¶ 15.)

In addition to his innovative microscopy work, Dr. Tafas has also developed an interest in the automotive arts. (Tafas Decl., at 19.) On November 4, 2005, Dr. Tafas caused a patent application to be prepared incorporating his new inventive concepts in the automotive arts. (Id., at ¶ 20.) In the first half of 2007, Dr. Tafas requested that new concepts be added to his patent application through the filing of a continuation-in-part application. Dr. Tafas was advised to file multiple continuation applications based on the USPTO's proposed rules. (Id., at ¶ 27.) Dr. Tafas chose to file three (3) continuation-in-part applications claiming priority to his original patent, relying on 35 U.S.C. § 120 to provide for further continuations as needed once he was financially able to file the same. (Id., at ¶ 27.). Such filings were finally effectuated on August 10, 2007.

THE LONG-STANDING PRIOR LAW REGARDING CONTINUATION FILINGS FOR PATENT APPLICATIONS

The Patent Act specifically sanctions the filing of voluntary-divisional continuation applications, continuation-in-part applications, and requests for continuing

examination of applications. Specifically 35 U.S.C. §§ 120 and 365 allow for the filing of voluntary-divisional continuation applications and continuation-in-part applications, while 35 U.S.C. § 132 allows for the filing of requests for continued examination ("RCEs").

A continuation application is an application that relates back to the filing date of a prior pending patent application filed by the same applicant for purposes of setting the date (the so-called "priority date") from which the inventiveness of elements of the claims will be adjudged. Prior to the Revised Rules, a continuation application could be framed as a voluntary or involuntary-divisional application, that is, respectively, an application which was caused to be filed by an applicant on the applicant's own volition, or an application which was caused to be filed by an applicant pursuant to a USPTO determination that the application contained more than one invention (a "restriction requirement"). A divisional-continuation application must include at least some portion of the text preceding the claims (the so-called "specification") of the parent application. If the entire text preceding the claims of the parent application is included in the divisional-continuation application, without the addition of any more text, the application has been referred to as a "continuation application" or "divisional application." If the entirety of, or part of, the text preceding the claims of the parent application is included in the divisional-continuation application, with the addition of other text, then the application is referenced as a "continuation-in-part application." A voluntary-divisional continuation application, which under the Revised Rules are defined as a "continuation application" (redefining the term "divisional" to exclude voluntary divisionals), may seek in its claims subject matter which was not originally sought to be patented in the parent application, but which finds support in the specification of the parent application.

Except under limited circumstances not applicable here, 35 U.S.C. §§ 120 and 365(c) confirm a patent applicant's right to file as many voluntary-divisional continuation applications and continuation-in-part applications as an applicant deems necessary and grants a patent applicant the benefit of the earlier filing date when filing an application for an invention disclosed, but not specifically claimed, in a previously filed application.

35 U.S.C. § 132 allows for the filing of a request for continuing examination ("RCE") of an application, that is a request for continuing the examination of a pending patent application so long as the claims are directed to substantially the same subject matter as originally submitted. 35 U.S.C. § 132(b) requires that the "[USPTO] Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." (emphasis added). No right, however, is granted in 35 U.S.C. § 132(b) authorizing the USPTO Director to limit the number of requests for continued examination.

THE RULE MAKING PROCESS FOR AND
ENACTMENT OF THE NEW REVISED RULES

On January 3, 2006 the USPTO published two (2) notices of proposed rule making 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") and "Changes to Practice for the Examination of Claims in Patent Applications" ("Proposed Rule II") (collectively the "Proposed Rules").[1] See 71 Fed. Reg. No. 1, 48 and 61.

[1] While proffering a number of town meetings to discuss its Proposed Rules, the USPTO specifically declined to hold any public hearings on its new proposals, such action flying in the face of In re Henriksen, 399 F.2d 253, 158 USPQ 224 (CCPA 1968), wherein that court noted "that it is for the Congress to decide with the usual opportunity for public hearing and debate, whether such a restriction [i.e., on continuation procedures] ... is to be imposed." Id. at 262. (emphasis added).

On August 21, 2007, the USPTO published its final rules in the Federal Register, which were a substantially modified version of the above referenced Proposed Rules at 72 Fed. Reg. No. 161 at 46716. The specific rules being challenged by Plaintiff are found at 37 C.F.R. § 178 ("Revised Rule I") and 37 C.F.R. § 175 ("Revised Rule II") (again, sometimes collectively the "Revised Rules"), which will become effective, unless preliminarily enjoined, as of November 1, 2007.

The Revised Rules require that patent applicants who file multiple voluntary-divisional continuation applications (seeking differing inventions flowing from the same initial application) and/or continuation-in-part applications must show to the satisfaction of the Director that the third and following applications in the chain are necessary to advance prosecution. Id. The Revised Rules also limit the right of an applicant to continue prosecution related to a single invention (a so-called "request for continuing examination" or "RCE"). Id.

Specifically, Revised Rule I requires that a third voluntary-divisional continuation application or a continuation-in-part application, be supported by showing by the applicant demonstrating why the amendment, argument, or evidence presented could not have been previously submitted. 37 C.F.R. § 1.78. Pursuant to Revised Rule I, the USPTO will deny an applicant the benefit -- as of right -- of a prior application in all third or subsequent voluntary-continuation application, or continuation-in-part application. Id. The Director is given the ability to deny the voluntary-divisional continuation application or the continuation-in-part application in his subjective discretion, even if the statutory requirements for filing a continuation application have been met. Id. Revised Rule I also limits applicants to only one (1) RCE.

Revised Rule I is retroactive and, as such, affects certain applications filed before the November 1, 2007 effective date of the Rule. 37 C.F.R. § 1.78. An applicant is only allowed two (2) continuations or continuation-in-part applications (or one of each) as of right after the effective date unless the applicant meets the requirements specified in Revised Rule I. Id. Outside of these limits, an applicant must petition the USPTO Director to file any other voluntary-divisional-continuations or continuation-in-part applications. See 72 Fed. Reg. No. 161, pp. 46776-46778. During the USPTO's town meeting on the Proposed Rules I and II, Commissioner Doll indicated that good cause for such petitions would be very limited.[2]

In addition, Revised Rule I creates the presumption that inventions are patentably indistinct if an applicant files multiple applications with the same filing date, or within two (2) months of such date and the applications include common inventors and overlapping disclosures. Revised Rule I requires that an applicant rebut this presumption with an explanation as to how the claims in the application are distinct or submit a terminal disclaimer explaining, to the satisfaction of the Director, why two (2) or more pending applications should be maintained. Id. If the Director does not accept such a rebuttal, one or more applications are not examined.

Revised Rule II requires persons filing applications containing more than five (5) independent claims (72 Fed. Reg. No. 161, pp. 46718) or twenty-five (25) total claims (Id.) must

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[2] Only three examples (3) were provided of when a petition to file a third continuation would be approvable: (1) a showing that an interference was being declared in an application containing both claims corresponding to the count(s) and claims not corresponding to the count(s), and the APJ suggests that the claims not corresponding to the count(s) be canceled and pursued in a separate application; (2) a showing that the provision of data necessary to support "unexpected results" just became (emphasis added) available to overcome a final rejection under 35 U.S.C. §103 and (emphasis added) the data is the result of a lengthy experimentation that was started after applicant received the rejection for the first time (n.b., this assumes the data was available before the office abandons an application due to the failure to file a continuation application during the pendency of the parent application); and (3) a showing that the final rejection contains a new ground of rejection that could not have been anticipated by the applicant and the applicant seeks to submit evidence which could not have been submitted earlier to overcome this new rejection.

provide the USPTO with an examination support document that addresses all of the claims.[3] 72 Fed. Reg. No. 161, p. 46724.

Due to the new rules concerning voluntary-divisional continuation applications, continuation-in-part applications, requests for continued examination practice, and the retroactivity under Revised Rule I, Dr. Tafas has been injured and has legal standing to bring this action. Dr. Tafas would not have disclosed all of his research in his previously filed and pending patent applications had he known the irreparable harm the Revised Rules would cause him in severely restricting both his legal right and practical ability to file future continuation applications. (Tafas Decl., ¶¶ 24-26).

ARGUMENT

PLAINTIFF SATISFIES THE PRELIMINARY INJUNCTION STANDARD

Preliminary injunction motions are decided pursuant to the framework established in Blackwelder Furniture Co. v. Seilig Mfg. Co., 550 F.2d 189 (4th Cir. 1977). In assessing such motions, "the district court must balance the hardships likely to befall the parties if the injunction is, or is not, granted." Hoeschst Diafoil Co. v. Nan Ya Plastics Corp., 174 F.3d 411,416-17 (4th Cir. 1999) (citing Blackwelder, 550 F.2d at 196). Specifically, the court must consider the following factors: "(1) the likelihood of irreparable harm to the plaintiff if the preliminary injunction is denied;(2) the likelihood of harm to the defendant if the requested relief is granted;

[3] The examination support document must set forth: (1) a statement that a pre-examination search was conducted, including identification of the USPTO field of search by class and sub-class, the date of the search, the databases used, and an identification of the search logic or chemical structure or sequence used as the query; (2) provide an Information Disclosure Statement ("IDS") in compliance with Section 1.98 citing the reference or references deemed most closely related to the subject matter of each independent claim; (3) an identification of all the limitations of the independent claims that are disclosed by the references cited; (4) a detailed explanation of how each of the independent claims are patentable over the reference cited; and (5) a showing of where each limitation of the independent claims finds support under 35 U.S.C. § 112, in the written description of the specification. 72 Fed. Reg. No. 161, at p. 46718.

(3) the likelihood that the plaintiff will succeed on the merits; and (4) the public interest." Id. at 417 (citations omitted).

Under the Blackwelder framework, the movant's likelihood of harm or lack thereof if the injunction is not granted relative to the harm, or lack thereof, to the non-movant if the injunction is granted affects the showing the movant must make with respect to it likelihood of success on the merits of its claims. That is to say, in instances as in the case before this Court now, where the potential harm to the movant is great if the preliminary injunction is not granted and the potential harm to the non-movant is slight if the injunction is granted, "it is enough that grave or serious questions [on the merits] are presented; and plaintiff need not show a likelihood of success." Blackwelder, 550 F.2d at 195-196. Compare Hoechst Diafoil, 174 F.3d at 417 (court may not grant preliminary injunction "where it is legally impossible for a plaintiff to succeed on the merits of its underlying claim . . . no matter how severe or irreparable an injury").

As set forth more particularly below, Plaintiff satisfies all four (4) of the Blackwelder factors and should, therefore, be entitled to a preliminary injunction preventing the Revised Rules from becoming effective *pendente lite*.

A. Plaintiff Is Likely to Succeed on the Merits of His Case

1. Defendants Exceeded The Statutory Authority Delegated To Them Under The Patent Act By Enacting The Revised Rule

a. The Applicable Statutes Mandate Unfettered Continuation Procedure

The Revised Rules exceed the scope of the USPTO's authority as conferred by Congress and are a *prima facie* violation of statutory law. The USPTO's sole authority for the Revised Rules is 35 U.S.C. § 2(b)(2), which provides that in certain instances the USPTO "may establish regulations, not inconsistent with law." 35 U.S.C. § 2(b)(2). Neither this general grant of rule-making authority nor any other statutory provision bestows any authority upon the

USPTO to limit the number of voluntary-divisional continuation or continuation-in-part filings or requests for continuing examination that may be filed with the USPTO.

More than 150 years ago, in Godfrey v. Eames, 68 U.S. 317, 323-325 (1863), the U.S. Supreme Court recognized the ability of an applicant to file a revised version of a patent application and withdraw the original while still retaining the original filing date. 35 U.S.C. § 120 codifies this principle as follows:

> An application for patent for an invention . . . filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.
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> * * * *

35 U.S.C. § 120.

So long as other conditions of patent application filing are met, a patent application "shall have" or "shall be" entitled to the benefit of the filing date of previously filed patent applications. 35 U.S.C. § 120. The mandatory "shall have" and "shall be" language in Section 120 is similarly utilized in 35 U.S.C. § 365(c), which also mandate that the benefit of the filing date of an earlier filed application is mandatory -- not optional at the discretion of the USPTO.

Under the Revised Rules, the USPTO will "refuse to enter, or will delete if present" the benefit of priority claimed to prior applications, in all third or subsequent voluntary-divisional divisional and continuation-in-part applications if a showing is not made to the satisfaction of the Director that such claimed subject matter could not have been pursued earlier. 37 C.F.R. § 1.78(d)(1). Thus, these Revised Rules imply that the USPTO has some

inherent authority to constrict and substantively limit long-standing continuation practice. However, as noted in In re Hogan, 559 F.2d 595, 194 USPQ 527 (CCPA 1977), "a limit upon continuation applications is a matter of policy for the Congress." Id. at 604 n.13 (quoting In re Henriksen, 399 F.2d 253, 262, 158 USPQ 224 (CCPA 1968)).

35 U.S.C. § 131 requires the Director to cause an examination to be made of the application and the alleged new invention. 35 U.S.C. § 131. Only under certain specifically enumerated limited circumstances, as specified in the Patent Act, may the USPTO deny an application. See e.g., 35 U.S.C. § 101 *et seq*. If the patent is rejected, or any objection or requirement is made, Section 132(a) of the Patent Act requires the Director to notify the applicant of the reasons for such rejection, objection or requirement. No provision is made in the Patent Act for the Director to examine only certain patent applications. Instead, the Patent Act clearly states that "the Director shall cause an examination to be made of the application and the alleged new invention...and if on such examination it appears that the applicant is entitled to patent under the law, the Director shall issue a patent therefore." 35 U.S.C. § 131. There is nothing that authorizes the USPTO Director to cause an examination to be made only upon a prior showing that the reasons for patentability could not have been made in an earlier filed application.

Under Revised Rule I, the USPTO creates a rebuttable presumption of patentably indistinct claims in two (2) or more applications that: (1) are filed on the same date; (2) name at least one inventor in common; (3) are owned by the same person; and (4) contain substantially overlapping disclosures. 37 C.F.R. § 1.78(f)(2). The rebuttable presumption arises without consideration of the claims in the respective applications. The USPTO does not have statutory authority to promulgate a rebuttable presumption. The patent examining process is a creature of

statute, premised on the notion that the inventor is entitled to a patent if the statutory requirements are met. 35 U.S.C. § 101 *et seq*. The Federal Circuit has ruled that "the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.... If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443 (Fed. Cir. 1992).

As such, a decision to substantively limit continuation practice is one that may only be made by Congress. In 2005, Congress considered changes similar to the Revised Rules. H.R. 2795, 109th Cong. § 123 (2005). The bill provided express language that would have expressly granted the USPTO Director the right to limit the circumstances under which a continuation application may be filed. Id. While a subsequent version of the bill eliminated this language, its original inclusion, however, provides support for the notion that only Congress has the authority to enact the Revised Rules and that Congress did not consider it appropriate to grant such authority to the Director.

In early August 2007, a bill was introduced in the House of Representatives which would add a new provision to 35 U.S.C. § 2 authorizing the USPTO to issue regulations concerning the quality and timeliness of applications and their examinations and "specifying the circumstances under which an application for patent may claim the benefit under Sections 120, 121, and 365(c) of the filing date of a prior filed application for patent." H.R. 1908, 110th Cong. (1st Sess. 2007). This further supports that the USPTO lacks the necessary statutory authority to promulgate the Revised Rules absent an express Congressional authorization.

b. Any Power Granted To The USPTO "To Advance Prosecution" of Applications Is Circumscribed By The Law As Interpreted By The Courts.

Pointing to the recently discovered doctrine of patent prosecution laches by several Federal Circuit panels, the USPTO has asserted that the Director has inherent authority under 35 U.S.C. § 2 to ensure that laches does not occur with respect to any patent application. The USPTO then seeks to bootstrap off this to suggest that prevention of laches empowers the USPTO to limit the number of continuing applications an applicant may file. 71 Fed. Reg. 48, 50. The USPTO asserts that In re Bogese II, 303 F.3d 1362, 64 USPQ2d 1448 (Fed. Cir. 2002) ("Bogese") "stands for the broad proposition that 35 U.S.C. § 120 does not give applicants *carte blanche* to prosecute continuing applications in any desired manner." 71 Fed. Reg. 48, 50.

Contrary to the USPTO's position, a careful reading of Bogese indicates that the majority of the three-member panel did not conclude that the USPTO has unfettered power to limit continuation practice under 35 U.S.C. § 120 et seq. Instead, the Bogese panel merely found that the USPTO has the power to reject an application in a case of an unreasonable delay in prosecution (*i.e.*, prosecution laches) as long as the applicant is afforded notice and an opportunity to correct the delay. Bogese, 303 F.3d at 1369. The three-member panel specifically distinguished the applicant in Bogese from an applicant who "maintain[s] pendency of an application . . .while competitor's products appear on the market. . ." implicitly accepting the later practice as being sanctioned under the law. Id. at 1369. In Bogese, the applicant had acted egregiously by repeatedly filing continuations as a procedural ruse to circumvent the need to respond to USPTO actions without ever amending the pending claims in any substantive manner. Significantly, the dissenting judge argued against even the limited power urged by the majority stating "nowhere however, has an agency been authorized to impose, in its discretion,

restrictions contrary to the statute that governs agency action." Id. at 1371 (Newman, J., dissenting).

The USPTO asserts that the Revised Rules serve to remedy abuses of unlimited continuation practice. 71 Fed. Reg. 48, 49. Continuing application filings are, however, already limited. Applicants cannot file an unlimited number of continuing applications. For example, under 35 U.S.C. § 154(a)(2) utility patents are limited to a term "beginning on the date on which the patent issues and ending 20 years [or sooner] from the date on which the application for the patent was filed in the United States...." 35 U.S.C. §154(a)(2).

As noted in the case of Ricoh Company Ltd. v. Nashua Corp., 185 F.3d 844, at 3, 1999 WL 88969, at 3 (Fed. Cir. 1999). "Section 120, governing continuation applications, does not contain any time limit on an applicant seeking broadened claims." (Unpublished, non-precedential decision). The Ricoh court approvingly cited to In re Hogan, 559 F.2d 595, 604 n.13, 194 USPQ 527, 536 (CCPA 1977) "[A] limit upon continuing applications ... is a matter of policy for Congress, not for us." Id.

The Patent Act expressly grants patent applicants the right to file continuation applications. As such, the Revised Rules substantively circumscribing those statutory rights are *ultra vires* and plainly exceed the delegation of rulemaking authority delegated to the USPTO by Congress.

2. The Revised Rules Violate The APA

a. The Revised Rules Violate the APA as They Are Retroactive Rule Making Without Express Statutory Authority.

(1) Changes in Agency Rules Are Only to Have Future Effects

The APA defines a "rule" as:

> the whole or part of an agency statement of general or particular applicability and future 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). The underlined phrase above explicitly suggests that rules must have legal consequences only for the future. The Supreme Court has disapproved of administrative agencies promulgating retroactive rules without express statutory authority to do so:

> Retroactivity is not favored in the law. Thus congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result...By the same principle, a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms. See Brimstone R. & Canal Co. v. United States, 276 U.S. 104, 122 (1928). ("The power to require readjustment for the past is drastic. It...ought not to be extended so as to permit unreasonably harsh action without very plain words"). Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.

Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("Bowen"). As Justice Scalia noted in his concurring opinion in Bowen, "a rule that has unreasonable secondary retroactivity – for example, altering future regulation in a manner that makes worthless substantial past investment incurred in reliance upon the prior rule – may for that reason be 'arbitrary' or 'capricious'... and thus invalid." Id. at 220.

(2) The Revised Rules Are Inequitable and Unreasonable Because They Retroactively Affect An Applicant's Substantial Investment

The Revised Rules apply to applications filed prior to the effective date of the Revised Rules and their retroactive application that essentially renders worthless, or at least substantially diminishes, the considerable past investments expended by Dr. Tafas in reliance on the prior continuation rules reflected in the Patent Act.

The Revised Rules have legal consequences both for existing practice and pending patent applications now before the USPTO. Under the prior continuation rules, applicants were free to liberally disclose as much information as possible about an invention, including tangentially related information which might also be separately patentable. Applicants were able to file as many voluntary-divisional continuations and continuation-in-part applications as necessary to claim various embodiments of their invention. Under the Revised Rules, however, it is up to the Director's subjective discretion to determine whether an applicant will get the benefit of a prior application in a third or subsequent voluntary-divisional-continuation and continuation-in-part applications. 37 C.F.R. § 1.78. The Revised Rules effectively bar patent applicants from claiming such embodiments and, therefore, adversely affect applications filed prior to the Rules' effective date to the serious detriment of applicants.[4]

b. The Revised Rules Violate the APA as They Are Arbitrary and Capricious

(1) In Enacting the Revised Rules Defendants Failed to Adequately Consider USPTO-Induced Reasons for Multiple Continuation Filings

Section 553(C) of the APA requires the USPTO to consider all relevant factors and information submitted to it as part of the rule-making process. 5 U.S.C. § 553(C). Section 706(2) of the APA provides that a reviewing court should find any agency action unlawful if the action is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law. 5 U.S.C. § 706(2)(A). An agency's decision is arbitrary and capricious under the APA if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency or is so implausible that it could not be ascribed to

[4] Again, an administrative rule that is applied retroactively against individuals who complied with the law is not appropriate. See In re Bogese II, 303 F.3d 1362, 1372 (Fed. Cir. 2002) (Newman, J. dissenting).

difference in view. Motor Vehicle Mfrs. Ass'n of U.S., Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). In making its determination as to whether rule making by an administrative agency is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law, a court should consider whether the agency's decision was based on an evaluation of the relevant factors and whether there has been a clear error of judgment. Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974).

Here, the USPTO failed to consider several very relevant factors in its rule making activities including, without limitation, substantial evidence submitted in response to the Proposed Rules that is contrary to the USPTO's assertions and findings in support of the Revised Rules.

One reason for RCEs and voluntary-divisional-continuations is the failure of a significant number of USPTO patent examiners to address new arguments of an applicant, but instead routinely copying and pasting prior office actions to make a new "count."[5] In the face of such an office action (generally after the first go around between the applicant and the examiner), the applicant has only two (2) choices – appeal the final rejection or refile a continuation application or RCE. As patent appeal practice is quite expensive, and the Board of Patent Appeals and Interferences has a backlog of cases, many applicants in the past have chosen to utilize continuation practice. The "count system" of the USPTO and the time allotted for review of each application (which has led to extremely overworked Examiners), has been widely criticized as incentivizing Examiners to spend less than an adequate time in reviewing

[5] An article published in Intellectual Property Today, titled "Hampering Ingenuity Through Changes in the Rules, The New USPTO Proposed Regulations" Intellectual Property Today, April 2006, 33-38, discusses a review of 24 randomly selected patent files where two or more office actions had issued. Of these 24 files, 11 of the files (nearly 46%) had office actions that were nearly identical, or substantially the same as one another (80% or more of the office action write-up was identical to a previous office action).

applications and applicants' responses to office actions (in fact, examiners are often given an impossible task to review long and complex applications within a small modicum of time). Although the USPTO could have investigated what percentage of three (3) or more voluntary-divisional continuations and RCEs were filed due to inappropriate Examiner office actions, the USPTO decided to turn a blind eye to the issue.

The USPTO also attempts to justify in part the limit on the number of voluntary-divisional applications, RCEs, and continuation in-part applications to, by blaming the practices of patent attorneys and agents: "The Office also notes that not every applicant comes to the Office prepared to particularly point out and distinctly claim what the applicant regards as his invention." 71 Fed. Reg. 48, 49.

However, the USPTO failed to consider whether the deficiencies of which it complains are due to its own failure in protecting the public from inadequately prepared practitioners. In particular, the USPTO failed to consider the inadequacy of its own examination procedures in admitting attorneys and agents to practice before it. In sharp contrast to the regulations of many foreign countries, there are no internships or practical training requirements required in order to practice before the USPTO. Many newly "USPTO qualified" attorneys and agents have little or no practical experience in claim drafting. They need only to pass a multiple choice test (that may be taken multiple times) to be registered by the USPTO as qualified to work on behalf of the general public. The USPTO has turned a blind eye to its inadequate admission policy.

The USPTO also failed to consider the number of continuation-in-part applications, RCEs, and amendments that are being filed due to imprecision in the English language (in fact, the imprecision in any language). For example, it is not uncommon for

continuation-in-part applications to be filed at the urging of the Examiner to include new definitions, or RCEs filed to clarify what is meant by a term or phrase.[6]

(2) Defendants Failed to Adequately Research The Impact of the Revised Rules on Small Entities (Individuals, Small Companies, and Research Universities)

5 U.S.C. § 605(h) requires any administrative agency to certify to the Chief Counsel for Advocacy of the Small Business Administration that changes to its regulations will not have a significant economic impact on a substantial number of small entities.

The USPTO failed to make an appropriate certification because it relied on a flawed statistical analysis to conclude that small entity filers would not be disproportionately impacted over large entity filers. First, instead of looking at multiple years prior to proposing its regulations, the USPTO choose to base its entire statistical analysis in the Proposed Rules on one isolated year, 2005. 71 Fed. Reg. No. 11, p. 57. In the Revised Rules, the USPTO chose to base its entire statistical analysis on one isolated year, 2006. 72 Fed. Reg. No. 161, p. 46760, 46788. No attempt was made to determine in either case whether such year was a typical filing year. Second, the USPTO choose to consider all applications used in their statistical analysis as having been filed by separate and distinct filers (irrespective of the fact that numerous large entities file hundreds, if not thousands, of patent applications a year). Third, the USPTO failed to check each applicant listed on an application to determine whether some of the applicants filing as "large

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[6] For example, a patent practitioner might assert as an element in a claim a "circumferential band." In drafting such element, the practitioner might well be envisioning a circular encircling strip of material. This interpretation is wholly within the bounds of the definitions of the words "circumferential." However, the Examiner might note a reference that includes a square-shaped strip of material. As one of the definitions of "circumference" includes "the external boundary or surface of a figure or object," there is an argument that the Examiner is correct in citing such art. A new filing would typically be required to more clearly specify what was intended.

entities" were truly "small entities" under the law.[7] Fourth, the USPTO in its statistical analysis failed to separate RCE practice, where the continuing practice relates to identical subject matter being claimed as in the parent application, from continuation practice, where the continuation application claims subject matter that is distinct from that claimed in a parent application.

The USPTO also failed to adequately assess the negative effect the Revised Rules will have on research universities, which are classified as small entities under 35 U.S.C. §§ 201, *et seq*. In its May 3, 2006 comments to the Proposed Rules, the Office of General Counsel of the University of Texas System stated that it disagreed with the USPTO's assessment that "a small percentage of university applicants use the continuation and CIP [continuation-in-part] practice."[8] The University of Texas surveyed the USPTO's own public records and found that approximately 32% of the total number of patents filed by the 19 most prolific research universities are continuations or CIP's.[9] Implementing the Revised Rules will consequently stifle innovation, sharply increase patent prosecution costs, reduce the incentive to fund research programs, and ultimately, "slow the transfer of new lifesaving drugs from universities to patients."[10]

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[7] As the USPTO knows, many attorneys file patent applications for their small entity clients under "large entity" status to avoid the possibility that the status of the client might change (due to a recognition by such attorneys that a failure to correct status might lead to the invalidity of a patent issuing from the application).

[8] Letter to Robert A. Clarke, Commissioner for Patents, from BethLynn Maxwell, Ph.D., J.D., Office of General Counsel, the University of Texas System (May 3, 2006), page 3.

[9] Id. These universities are the University of California, MIT, University of Texas System, Cal Tech, University of Wisconsin, Cornell Research, University of Florida, University of Michigan, University of Minnesota, Iowa State, Columbia University, University of Pennsylvania, State University of NY, Harvard, Duke University, Michigan State University, University of Washington, North Carolina, and Stanford.

[10] Id. at 4.

(3) Defendants Failed to Adequately Research the Effects of Its Pre-Examination Search Report Requirement

The USPTO relied on flawed statistics in enacting its pre-examination search report requirement for applicants identifying more than a specified number of claims for examination. The USPTO points to a 2003 AIPLA economic survey as providing support for the proposition that in 2006 a patent search of the scope required for a pre-examination search would be about $2,500. 71 Fed. Reg. No. 1, p. 66. Such statement, however, was made without any investigation into standard patent novelty search practice in 2002 which forms the basis of the 2003 AIPLA economic survey.

As would be known to anyone of skill in the art, patentability searches as described in the AIPLA report, have absolutely no correlation to the type of pre-examination search report being imposed by the USPTO. The USPTO's estimate that the burden of its change would equate to an additional 1 minute and 48 seconds to 12 hours of work for applicants, inclusive of all the search time on each claim, analysis of references uncovered, placing the same into the required report, filing the IDS, etc., 71 Fed. Reg. 48, 58, is simply a flight of fantasy having no basis in statistics or reality. The USPTO's Revised Rules indicate only that an analysis of the final rule's impact on small entities was made, and that this new analysis suggested a cost of $2,563 to $13,121 for the average small entity filer. 72 Fed. Reg. No. 161, p. 46798. No basis for such an analysis is set forth. The USPTO appears to have completely ignored the effect of the Revised Rules on large entity filers and the total effect of its Revised Rules on the progress of the sciences and useful arts.

The Small Business Administration Office of Advocacy has stated that the Revised Rules "are likely to have a significant economic impact on a substantial number of small entities, including small businesses and small independent inventors" and that "[c]ontrary to the

PTO's estimates...completion of an examination support document could cost from $25,000 to $30,000 – a significant outlay."[11] In the biotechnology and pharmaceutical sectors, where patent applications generally require more than ten (10) representative claims to accurately address the entire scope of the invention, a single examination support document is estimated to cost $50,000 – $100,000.[12] Small to mid-sized biotechnology and pharmaceutical companies, as well as independent inventors, generally cannot afford to regularly prepare these support documents and consequently, will be forced to accept less patent coverage than they are entitled to under the patent laws.[13] The result of such choices will be to inhibit investment in research and development.[14]

3. The Revised Rules Violate The United States Constitution

a. Defendants Violated Article I, Section 8, Cl. 8, of the United States Constitution in That They Failed to Adequately Consider Whether the Revised Rules Interfered with the Promotion of Science and the Useful Arts

The Constitution of the United States gives Congress the power to enact laws relating to patents, in Article I, Section 8, which reads "Congress shall have power . . . to promote the progress of science and useful arts, by securing, for a limited time, to authors and inventors the exclusive right to their respective writings and discoveries." U.S. Const. Art. 1, § 8. In exercising its patent power, Congress may not overreach the restraints imposed by the stated constitutional purpose. Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 5-6 (1966) ("Graham"). Of all the powers granted to Congress pursuant to Article I of the Constitution, only the power in Section 8 is specifically limited to a particular purpose. In Graham, the

[11] SBA comments at 71 Fed. Reg. 61, page 3 (April 28, 2006).

[12] Zymogenetics, Inc. comments at 71 Fed. Reg. 61, page 1 (May 3, 2006).

[13] Id. at 2.; Amalyin Pharmaceuticals, Inc. comments at 71 Fed. Reg. 61, pages 1-2 (May 3, 2006).

[14] Id.

Supreme Court noted that "Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the progress of useful arts.'" Id. at 6 (emphasis added).

Congress may delegate its power to make rules and regulations to an administrative agency. See Bowen, 488 U.S. at 208. However, the rule-making authority delegated to administrative agencies by Congress is limited by the statute conferring the power, and ultimately limited by Congress's Article I powers. Id. When enacting administrative rules, governmental agencies must act within constitutional parameters and consistent with existing statutes. A reviewing court must hold unlawful and set aside any agency actions not in accordance with the law, 5 U.S.C.A. § 706(2)(A), whether the law is statutory-based or constitutional-based.

Here, the USPTO's power to establish regulations that are not inconsistent with the law stems from 35 U.S.C. § 2. Therefore, because Congress established the USPTO to issue patents on behalf of the government, the USPTO must specifically consider the impact of its regulations on the progress of science and the useful arts when enacting regulations. Nowhere in the comments published by the USPTO concerning either the Proposed Rules or Revised Rules is there any indication that the USPTO performed an adequate and reasoned weighing of the pros and cons of its Revised Rules in light of the present statutory and regulatory framework, critically and expressedly considering whether the Revised Rules actually "promote the Progress of Science and Useful Arts" as required by the Constitution.

The primary reason for the Revised Rules is not to promote the progress of science and useful arts, but instead to simply reduce the USPTO's workload by reducing the volume of applications it receives. This is evidenced by the USPTO's statement in its Comments

on the Revised Rules that: "The former unrestricted continued examination practice was impairing the office's ability to examine new applications. As a result, the office is modifying continued examination practice in this final rule to address the backlog of unexamined new applications." 72 Fed Reg. No. 161 at p. 46790.

The USPTO's admitted reason for altering continuation practice simply does not fulfill the constitutional mandate that the USPTO consider the effects of its regulations on the promotion of the progress of science and the useful arts. The USPTO's failure to hire examiners appropriately in the past to deal with an increase in patent application filings simply does not justify restricting continuation practice, which does not promote and, in fact, retards the promotion of the progress of science and the useful arts.[15]

The USPTO's constitutional duty with respect to its regulations is much more than simply mimicking back the purpose of the patent system, but instead to promote the progress of science and the useful arts. It is not enough for the USPTO to merely cite to some perceived abuses which it feels need to be addressed, but also to actually investigate and weigh in a detailed manner whether its proposed regulations interfere with the progress of science and

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[15] Illustrative of this is that the University of Texas System presented data in opposition to the Proposed Rules asserting that only one of the eight most currently used cancer drugs would be on the market under the Proposed Rules (which allow only one (1) continuation or RCE application as of right). Only Epogen is protected by patents having only one continuation, RCE or continuation-in-part and containing ten or fewer claims, as originally proposed in Proposed Rule I. The remaining seven drugs – Procrit/Eprex, Eloxatin, Gleevec/Glivec, Gemzar, Lupron, Taxotere, and Herceptin – are protected by patents that resulted from more than one continuation, RCE or continuation-in-part and contained more than ten (10) claims. These seven drugs have helped countless numbers of patients and account for approximately 37% of the cancer market. See University of Texas System Comments to 71 Fed. Reg. 48 and 61, page 2 (May 3, 2006). Even under the more liberal standards set forth in Revised Rule I (however, with the USPTO reserving the right to further constrict continuation practice at its will), three (3) of these drugs, Herceptin, Procrit/Eprex, and Gemzar, may not have received the extent of patent protection necessary for their respective developers to undertake the clinical investment necessary to bring the products to market.

the useful arts in contradiction to Constitutional and statutory mandates. The USPTO failed in that duty in enacting the Revised Rules.

b. Defendants Violated the Fifth Amendment of the United States Constitution in That the Application of the Revised Rules is Retroactive

It is well established under statutory and common law that the possessor of an issued patent has property rights in that patent. 35 U.S.C. § 261 ("[P]atents shall have the attributes of personal property."); see also Consol. Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1876) ("A patent for an invention is as much property as a patent for land."); Florida Prepaid Postsecondary Educ. Expense Bd v. Coll. Sav. Bank, 527 U.S. 627, 642 (2002) ("Patents, however, have long been considered a species of property."); Cammeyer v. Newton, 94 U.S. 225, 226 (1876) ("the right of the [patent] holder is as much entitled to protection as any other property"). As property, patents are subject to the Fifth Amendment of the United States Constitution which states that no person shall be "deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

Based on the regulations prior to the Revised Rules and as required by patent law, Dr. Tafas fully disclosed his original ideas in the Tafas Patent Application with the reasonable expectation of filing as many voluntary-divisional and continuations, and requests for continuing examinations and continuations-in-part as might prove necessary to secure patents on his work. (Tafas Decl., ¶¶ 16-17). The retroactive application of the Revised Rules effectively denies Dr. Tafas the ability to claim priority to all his patentable ideas back to the original filing date of the Tafas Patent Application. In short, Defendants have severely limited and/or destroyed the rights of Plaintiff (and other similarly situated inventors) to patent their original ideas and thus deprived Plaintiff of his property without due process of law in violation of his Fifth Amendment rights.

"Although Congress is not required to create intellectual property rights at all, once it has done so, there may be some constitutional constraint upon retroactive modification to those rights . . . The Supreme Court has long recognized that the federal government, as well as the states, ought not change expectations retroactively, particularly to impair previously conferred benefits supported by investment-backed expectations." Price, PROPERTY RIGHTS Ch. 4, at 8 (ABC-CLIO, 2003).

In determining whether a taking has occurred, courts consider three factors: (1) the economic impact of the regulation on the claimant; (2) the extent to which the regulation has interfered with distinct investment-backed expectations; and (3) the character of the governmental action. Penn Central Transportation Co. v. City of New York, 438 U.S. 104, 124 (1978). By retroactively denying Dr. Tafas his right to file multiple continuation applications, Defendants have effected a taking that satisfies these three (3) factors. The Revised Rules clearly have interfered with Dr. Tafas's reasonable and distinct investment-backed expectation that he would be able to file multiple continuation applications and patent his ideas in the future.

In Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003 (1984), the Supreme Court found that there are property rights in many forms of intangible property, including trade secrets, liens and contracts, and that such property rights are protected by the Fifth Amendment. The Court held that a retroactively applied law which allowed a government agency to consider or disclose an entity's trade secrets constitutes a taking under the Fifth Amendment. Id.

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

right), Dr. Tafas relied on the exclusivity that results from the *quid pro quo* between a patent applicant and the federal government. Dr. Tafas met his part of the *quid pro quo* bargain by fully disclosing his ideas in his patent applications. However, as a result of the Revised Rules, Dr. Tafas will be unable to pursue each claim filed in his original application.

B. Plaintiff Will Suffer Irreparable Injury If the Injunction Is Not Granted.

Dr. Tafas will suffer irreparable injury if this court does not grant a preliminary injunction restraining the effectiveness of the Revised Rules *pendente lite*. In reliance on the law and regulations prior to the enactment of the Revised Rules, Dr. Tafas disclosed all the research related to his invention in the Tafas Patent Applications, reasonably believing he would be able to file multiple continuation applications based on the inventive concepts broadly disclosed therein. Since the Revised Rules purport to apply retroactively to currently pending patent applications filed prior to the effective date of the Revised Rules, Dr. Tafas has been injured because he is no longer able to rely on an ability to file additional voluntary-divisional continuations, RCEs, or continuation-in-part applications to protect his right to patent his inventions.

As discussed in the Tafas Declaration, continuation practice is very much a necessity for individual inventors such as Dr. Tafas, as well as for small corporations and research universities. Again, frequently these types of entities cannot afford to pursue each of their ideas simultaneously. Having obtained patent protection on their core ideas, they later file continuation applications to patent other inventive concepts covered in their initial disclosures. In this way, they are able to spread their legal costs and increasingly expensive USPTO filing fees over several years, while simultaneously ensuring their right of first priority to their ideas.

As Dr. Tafas has already filed two (2) or more continuation-in-part applications, and must petition the Director to file a third application on the basis of lack of funds to have filed such applications in the past, it is clear that Dr. Tafas will suffer irreparable harm from the Revised Rules, among other reasons, because the USPTO makes clear in its Revised Rules that a lack of funds will not support a petition for further filing. 71 Fed. Reg. No. 161, p. 146775.

C. **An Injunction Will Not Substantially Injure Other Interested Parties.**

Granting a preliminary injunction in this matter will not substantially injure other potentially interested parties. A patent applicant's right to file continuation applications was first recognized by the United States Supreme Court in Godfrey v. Eames, 68 U.S. 317 (1863) and is statutorily protected under 35 U.S.C. § 120. The issuance of a preliminary injunction in this case will simply maintain the existing standards for the examination of patent claims -- standards that American researchers and inventors have relied upon for many, many years -- until a final judgment on the merits of the present action.

D. **The Issuance of Preliminary Injunction Will Further the Public Interest.**

Following the original publication of the Proposed Rules in the Federal Register on January 3, 2006, approximately five hundred (500) organizations and individuals issued public comments to the USPTO arguing against their implementation, including, without limitation, an advisory group of the U.S. Small Business Administration, the American Intellectual Property Law Association, the Intellectual Property Law Section of the American Bar Association, and the Patent Public Advisory Committee of the United States Patent and Trademark Office (the "PPAC"). The negative comments received overwhelmingly outweighed the few positive comments. It is believed no proposed regulations in USPTO history have ever received so much negative comment. The general outcry against the enactment of the Revised

Rules among members of the patent community and patent bar further demonstrates that the enactment of the Revised Rules is detrimental to the public interest. More importantly, given the magnitude and gravity of the proposed change after more than 150 years of expansive and guaranteed continuation practice, it is in the public interest that the status *quo ante* be maintained until a final decision on the merits of Plaintiff's underlying claims.

The USPTO asserts the Revised Rules are a reaction to a continuing "abusive" examination practice by many supposedly careless applicants who rely "on an unlimited number of continued examination filings to correct deficiencies in claims and disclosures that applicant or applicant's representative have not adequately reviewed." 71 Fed. Reg. 48, 49. However, as the PPAC publicly commented, the USPTO has failed to demonstrate such stringent limitations on all patent applications are necessary, given that only a few "truly burden the Office in an inordinate way."[16] The PPAC further commented that the Revised Rules in their proposed form would "subject applicants to an unreasonable risk of loss of right ... simply as a consequence of the administrative process...."[17] In any event, even assuming *arguendo* that the liberal scope of continuation practice expressly afforded to patent applicants by express Congressional legislative enactment is being abused by some applicants, only Congress -- not the USPTO -- has the authority to amend 35 U.S.C. §§ 120, 132 and 365 so as to substantively circumscribe long-standing continuation rights.

Continuation practice promotes a public good in allowing inventors to disclose their inventions at the earliest possible time, without fear that such disclosure will count against them in any subsequent applications. The issuance of a preliminary injunction prohibiting the

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[16] Letter to the Honorable Jon Dudas from Rick D. Nydegger, Chair of the Patent Public Advisory Committee of the United States Patent and Trademark Office, May 3, 2006, at page 5.

[17] Id. at 19.

enactment of the Revised Rules will permit inventors and researchers freely to disclose all their research, confident that they will receive the benefit of their earliest filing date on all subsequent iterations of their work. Again, full disclosure promotes innovation and investment in new research, and thus benefits the public. Allowing the implementation of the Revised Rules will be detrimental not only to Dr. Tafas and thousands of inventors like him, but to the public in general. The resulting loss of rights to full patent protection will act as a disincentive to investment in research, particularly in the biotechnology and pharmaceutical fields, with serious consequences for public access to new drugs and medical procedures.

CONCLUSION

WHEREFORE, Plaintiff respectfully requests that the Court enter an Order in the proposed form included herewith, enjoining Defendants from implementing the Revised Rules and maintaining the *status quo* pending a final judgment of this Court on the merits, along with such, other, further and different relief as the Court deems just, equitable and proper.

Respectfully submitted,

Joseph D. Wilson (VSB # 43693)
KELLEY DRYE & WARREN LLP
Washington Harbor, Suite 400
3050 K Street, NW
Washington, DC 20007
Telephone: (202) 342-8400
Facsimile: (202) 342-8451
E-mail: jwilson@kelleydrye.com

Counsel for Plaintiff Triantafyllos Tafas

Of Counsel:

William R. Golden Jr., Esq.
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178-0002
Telephone: (212) 808-7992
Facsimile: (212) 808-7897
E-mail: wgolden@kelleydrye.com

--and--

Steve J. Moore, Esq.
James E. Nealon, Esq.
KELLEY DRYE & WARREN LLP
400 Atlantic Street
Stamford, Connecticut 06901-3229
Telephone: (203) 324-1400
Facsmile: (203) 327-2669
E-mail: smoore@kelleydrye.com
jnealon@kelleydrye.com

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