

**United States Court of Appeals**  
*for the*  
**Federal Circuit**

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TRIANTAFYLLOS TAFAS,

*Plaintiff-Appellee,*

– and –

SMITHKLINE BEECHAM CORPORATION (d/b/a GlaxoSmithKline),  
SMITHKLINE BEECHAM PLC and GLAXO GROUP LIMITED  
(d/b/a GlaxoSmithKline),

*Plaintiffs-Appellees,*

– v. –

JON DUDAS, Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office,  
and UNITED STATES PATENT AND TRADEMARK OFFICE,

*Defendants-Appellants.*

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APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN  
DISTRICT OF VIRGINIA IN CONSOLIDATED CASE NOS. 1:07-CV-846 AND  
1:07-CV-1008, SENIOR JUDGE JAMES C. CACHERIS

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**BRIEF OF *AMICUS CURIAE* NEW YORK INTELLECTUAL  
PROPERTY LAW ASSOCIATION IN SUPPORT OF APPELLEES**

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## **CERTIFICATE OF INTEREST**

The undersigned counsel of record for *amicus curiae* New York Intellectual Property Law Association hereby certifies the following:

1. The name of every party or *amicus curiae* represented by me or by the other below-identified attorneys in connection with this proceeding is: New York Intellectual Property Law Association.

2. The name of the real party in interest (if such party is not named in the caption of this brief) is: New York Intellectual Property Law Association.


3. The parent companies, subsidiaries (except wholly-owned subsidiaries), and affiliates of the party or *amicus curiae* represented by me and that have issued shares to the public, are: None.

4. The names of all law firms and partners or associates that appeared for the parties or *amici* now represented by me in the trial court or agency and who are expected to appear in this Court are indicated below.

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**STATEMENT OF IDENTITY, INTEREST, AND AUTHORITY**  
**OF AMICUS CURIAE UNDER FED. R. APP. P. 29(c)(3)**

The New York Intellectual Property Law Association (“NYIPLA”) submits this brief as *amicus curiae* in support of appellees in order to explain why the Patent and Trademark Office’s (“PTO’s”) Final Rules,<sup>1</sup> for which there is no defensible statutory basis, and hence are *ultra vires*, would have a serious adverse impact on creators, owners, and legitimate users of patent assets. The April 1, 2008 judgment of the district court permanently enjoined the implementation of the Final Rules as constituting unlawful substantive rulemaking beyond the PTO’s statutory authority, and whose bases according to the PTO’s own interpretations are entitled to no judicial deference.<sup>2</sup> Reversing any part of that judgment would set a dangerous precedent that would enable the PTO, an administrative agency, to assert in the future the kind of power it now seeks in order to do what in effect would be tantamount to making substantive changes in patent law. For the reasons set forth in this brief, the judgment of the district court should be affirmed in its entirety.<sup>3</sup>

In accordance with Fed. R. App. 29(a), all parties to this appeal, through their respective counsels of record, orally consented on September 30, 2008 to the submission of this brief.

*Amicus curiae* NYIPLA and its counsel appearing in this proceeding represent that they have authored this brief, that no counsel for a party authored this brief in whole or in part, and that no counsel or party made any monetary

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<sup>1</sup> See *infra* notes 6 and 7.

<sup>2</sup> *Tafax v. Dudas*, F. Supp. 2d 805 (E.D. Va. 2008).

<sup>3</sup> The NYIPLA’s silence on points and issues not addressed in this brief does not mean that the NYIPLA agrees with positions taken by appellants on those points and issues.

contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* NYIPLA, its members, or its counsel made any monetary contribution to the preparation or submission of this brief. The arguments set forth in this brief were approved on October 2, 2008 by an absolute majority of the total number of officers and members of the Board of Directors of the NYIPLA (including such officers and Board members who did not vote for any reason including recusal), but do not necessarily reflect the views of a majority of the members of the NYIPLA or of the firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer, or member of its Board or Amicus Committee who voted in favor of this brief, or any attorney in the law firm or corporation of such an officer, Board or Committee member, or attorney who aided in preparing this brief, represents a party with respect to this litigation. Some officers, Board or Committee members or other attorneys in their respective law firms or corporations may represent entities, including other amici curiae, which have an interest in other matters that may be affected by the outcome of this litigation.

The NYIPLA is a bar association of approximately 1,600 attorneys whose professional interests and practices lie mainly in the areas of patents, copyrights, trademarks, trade secrets and other forms of intellectual property (“IP”). NYIPLA members include in-house attorneys serving businesses and other organizations that deal with IP rights in all technologies and disciplines, as well as attorneys in private practice who represent IP owners and their adversaries. Parties that are served and represented include individual inventors, entrepreneurs, venture capitalists, companies, universities, and industry and trade associations. NYIPLA members represent both plaintiffs and defendants in IP

litigation and regularly participate in matters before the PTO, including the prosecution of patent applications and other proceedings before the agency.

Founded in 1922, the NYIPLA has achieved national recognition by its continuous, historic commitment to maintaining the integrity of the United States patent system, and to the proper application and observance of United States patent law by courts and agencies. Noteworthy in that regard are the contributions made by the Honorable Giles S. Rich, a celebrated member of this Court and its predecessor, the Court of Customs and Patent Appeals. While serving as the NYIPLA's 28th President (from 1951 to 1952) he was instrumental in the drafting and enactment of, and contributed to the preparation of an official commentary on, the Patent Act of 1952 embodied in title 35 of the United States Code (hereinafter referred to in its current form as the "Patent Act").<sup>4</sup> Later, during his career both as a patent lawyer and then as a jurist, Judge Rich continued to contribute significantly to the promotion of the Patent Act's vitality and relevance to both the American and global economies. Since then, the expeditious, efficient, and economical operation of the PTO, in accordance with sound administrative law principles, as embodied in the Patent Act, remains what is arguably one of the most important factors affecting the innovation-driven economy and well-being of the United States.

The NYIPLA supports ongoing review of the PTO's practices and procedures aimed at improving the patent examination process and the quality of patents issued by the agency. The NYIPLA is mindful of the PTO's attempts to manage the ever-increasing number of initial and continuing patent applications

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<sup>4</sup> See *Tafas* Brief at 28.

filed and pending each year,<sup>5</sup> as well as the “large and growing backlog of unexamined patent applications”<sup>6</sup> by reducing the period between filing and allowance. Foreclosing patent applicants from exercising their long-standing rights under the Patent Act by inflicting upon them the present rulemaking that exceeds the PTO’s statutory authority under 35 U.S.C. § 2(b)(2) to “establish regulations, not inconsistent with law,” is not a valid option. The NYIPLA believes that the challenges facing the PTO as alluded to in the agency’s brief stem from issues that can and should be addressed by statutorily permissible rulemaking and by applying existing disciplinary rules that are intended to curb abuses in the filing of patent applications.

### **SUMMARY OF ARGUMENT**

The PTO’s “Final Rules”<sup>7</sup> are unlawful because they entail significant changes in our patent system that would have negative consequences adversely affecting the *substantive* rights of patent applicants. The PTO’s existing administrative rules governing the filing of overlapping patent applications, continuing applications, requests for continued examination (“RCEs”) and the number of claims in an application are well-established features of the U.S. patent system, and are grounded on and are consistent with fundamental principles of statutory patent law. The Final Rules, however, would impose

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<sup>5</sup> In 2004, 2005, 2006, and 2007 the PTO received respectively 378,984; 409,532; 445,613; and 467,243 patent applications, and had total patent application pendencies of 27.6%; 29.1%; 31.1%; and 31.9% of total cases filed. (Source: PTO’s Performance and Accountability Report for Fiscal Year 2007).

<sup>6</sup> 72 Fed. Reg. 46717, 46790 (Aug. 21, 2007).

<sup>7</sup> *Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications; Final Rule*, 72 Fed. Reg. 46716 - 46843 (Aug. 21, 2007).

undue restrictions and obligations that alter long-established substantive, statutory rights of patent applicants.

According to the Patent Act and controlling judicial precedent, the PTO may only promulgate rules affecting *administrative procedures*; it may not enact legislative rules that alter the *substantive rights* of parties appearing before it, which in this case would include patent applicants whose rights under 35 U.S.C. § 112 and 35 U.S.C. § 120 would be jeopardized under the Final Rules.<sup>8</sup> Congress delegated to the PTO the responsibility for granting and issuing patents in accordance with what is now 35 U.S.C. § 2(a) and for examining patent applications and conducting other proceedings in accordance with § 2(b). In the context of this case, the PTO must exercise its responsibilities consistent with the statutory rights and standards set forth in 35 U.S.C. § 112, second paragraph (governing the number of claims in patent applications), and § 120 (governing the number of continuing applications that inventors may file).

To justify its attempt to alter the substantive rights that patent applicants have always had under 35 U.S.C. § 112 and 35 U.S.C. § 120, the PTO interprets those statutes in a manner that is not only at odds with their plain wording and intent, but unreasonable as well. In doing so, the PTO exceeds

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<sup>8</sup> The Final Rules are **37 C.F.R. § 1.78(d)(1)(i) - (vi)** (permitting the filing of only up to two continuing applications as a matter of right); **37 C.F.R. § 1.78(f)** (for multiple applications having overlapping inventorships, disclosures, and filing dates); **37 C.F.R. § 1.114(f) - (h)** (permitting the filing of only one request for continued examination or “RCE” as a matter of right); **37 C.F.R. § 1.75(b)(1) - (5)** (limiting the number of claims in patent applications to 25 total claims including 5 independent claims in the absence of an “Examination Support Document” or “ESD”); and **37 C.F.R. § 1.265** (requirements for ESDs). References herein to particular Final Rules are made using the prefix “FR” or “Rule” in lieu of “37 C.F.R. §.” Thus, for example, the Final Rule in 37 C.F.R. § 1.78(d) is referred to as “FR 1.78(d)” or “Rule 78(d).”

its authority as an administrative agency. Hence, such interpretations are *ultra vires* and are entitled to no deference by any court.

In seeking to justify its Final Rules as a means for reducing the backlog and pendency of patent applications, the PTO seems to have paid little if any attention to its existing practitioner disciplinary rules. By providing standards of conduct before the PTO that are enforceable by the agency, the disciplinary rules provide an effective alternative for curbing whatever abusive practices the PTO perceives in the filing of continuing applications and RCEs.

The PTO's rulemaking in this case would usurp Congress's exclusive authority to legislate and in so doing raises serious issues for the courts and IP owners. Affirmance of the judgment of the district court would re-confirm the proper statutory limits to the PTO's rulemaking authority. Otherwise, the PTO would have a judicially sanctioned precedent for asserting enlarged rulemaking authority in the future, a power that Congress never intended to delegate to the PTO. This would enable the PTO to change, rather than simply administer, other substantive aspects of the patent system in a manner exceeding the agency's lawful authority. The consequences that would flow from promulgation of the Final Rules would be far-reaching and of no benefit to the patent community.

### **SUMMARY STATEMENT OF BACKGROUND FACTS**

To administer its legislative power under U.S. Const. art. I, § 8, cl. 8,<sup>9</sup> Congress established the PTO<sup>10</sup> and conferred upon it specific, administrative

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<sup>9</sup> U.S. Const. art. I, § 8, cl. 8 empowers Congress “[t]o promote the Progress of . . . [the] useful Arts by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”

<sup>10</sup> 35 U.S.C. § , first sentence (“The United States Patent and Trademark office is established as an agency of the United States, within the Department of Commerce.”)

gate-keeping duties, including receiving and examining patent applications and granting patents in proceedings officiated by a corps of examiners.<sup>11</sup> In that capacity, the PTO performs one of the oldest administrative functions of any agency in the executive branch of the federal government.<sup>12</sup> In the context of this case, those functions must comport with the language in 35 U.S.C. § 112, second paragraph (governing the number of claims in a patent application), and 35 U.S.C. § 120 (governing the number of continuing applications that may be filed). The Final Rules fail to do so.

Congress purposely delegated *limited and specific* powers to the PTO “to establish regulations, not inconsistent with law, which – (A) shall govern the conduct of proceedings in the Office,”<sup>13</sup> and “(C) shall facilitate and expedite the processing of patent applications....”<sup>14</sup> Pursuant to its statutory mandate and responsibility, what the PTO is supposed to do and what is expected of those appearing before it are set forth in administrative rules promulgated by the agency in title 37 of the *Code of Federal Regulations*<sup>15</sup> and commonly known as

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<sup>11</sup> 35 U.S.C. § 2(a) (“[In general, the PTO], subject to the policy direction of the Secretary of Commerce – (1) shall be responsible for the granting and issuing of patents . . .”). More particularly, 35 U.S.C. § 131 provides that “[t]he 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 a patent under the law, the Director shall issue a patent therefor.”

<sup>12</sup> Following the enactment of this country’s first federal patent law, 1 Stat. 109-112 (1790), the granting of patents was initially administered through the State Department. In 1802, a separate bureau headed by a “Superintendent of Patents,” was formed within the Department to perform that role. In 1836, the Patent Office was established as an independent agency, and eventually it became an agency within the Department of Commerce where it remains to this day. See *supra* note 10.

<sup>13</sup> 35 U.S.C. § 2(b)(2)(A).

<sup>14</sup> 35 U.S.C. § 2(b)(2)(C).

<sup>15</sup> In addition, the *Manual of Patent Examining Procedure* (“MPEP”), which has been characterized as published guidelines “that both examiners and applicants must follow during the patent application process,” sets forth the

the PTO *Rules of Practice*. Such rules are administrative—not legislative—because they expressly define and specifically cabin the PTO’s rulemaking authority within the confines of the agency’s *management* of its own operations in accordance with Part I of the Patent Act and the *administration* of provisions in other parts of the Patent Act.<sup>16</sup> The PTO is thus purely “an administrative agency”<sup>17</sup> whose purpose and authority are circumscribed by the Patent Act.<sup>18</sup> As such, the PTO differs fundamentally from “regulatory” agencies, which operate according to their own substantive regulations promulgated pursuant to legislative rulemaking powers delegated to those agencies for that purpose by Congress. In contrast, the PTO, by its very nature has no lawful authority to set its own standards of substantive law or policy. Rather, its role is limited by statute to formulating and issuing interpretive and procedural administrative rules

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Patent Office’s “official interpretation” of the governing statutes and administrative Final Rules. Such interpretation must be consistent with congressional intent and judicial construction. *Geneva Pharms., Inc. v. GlaxoSmithKlein PLC*, 189 F. Supp. 2d 377, 383 n. 7 (E.D. Va. 2002), *aff’d*, 349 F.3d 1373 (Fed. Cir. 2003); *Enzo Biochem. Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002); *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984) (“The MPEP has no binding force on us, but is entitled to notice so far as it is an official interpretation of statutes or regulations with which it is not in conflict”). Citations to the MPEP in this brief are with reference to the 7th revision (July 2008) of the 8th edition (2001).

<sup>16</sup> 35 U.S.C. § 1(a) (“In carrying out its functions, the [PTO] shall be subject to the policy direction of the Secretary of Commerce, but otherwise shall retain responsibility for decisions regarding the management and administration of its operations and shall exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with this title and applicable provisions of law.”)

<sup>17</sup> *Black’s Law Dictionary*, 63(3) 7th ed. (1999) defines the term “administrative agency” as a “governmental body with the authority to implement and administer [not tamper with] particular legislation.”

<sup>18</sup> *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1365-68 (Fed. Cir. 2002) (“The PTO is an administrative agency that is “responsible for the granting and issuing of patents . . . 35 U.S.C. § 2 (2000).”)

(title 37 C.F.R.) relating to, for example, patent applications. Such rules must conform to statutory standards of substantive law legislated by Congress and whose interpretation is exclusively reserved for the courts.<sup>19</sup>

### **ARGUMENT**

The Final Rules are a manifestation of unlawful agency action under 5 U.S.C. § 706(a) inasmuch as they are substantive in nature, change existing law, and alter the rights and legal interests of patent applicants rather than merely the formal manner in which their applications are presented to the PTO. As such the Final Rules should be adjudged null and void.

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<sup>19</sup> 35 U.S.C. § 2. See, e.g., *Mannington Mills, Inc. v. Congoleum Corp.*, 595 F.2d 1287, 1294 (3d Cir. 1979) (“[t]he granting of . . . patents per se [is] in substance [a] ministerial activity.”); *Brenner v. Ebbert*, 398 F.2d 762, 764 (D.C. Cir. 1968) (“[The] issuance of [a] patent . . . is a relatively ministerial act . . . .”); *Nobelpharma AB v. Implant Innovations, Inc.*, 930 F. Supp. 1241, 1253 (N.D. Ill. 1996) (noting that a patent examiner is a “ministerial official whose function is to apply policy set by others . . . to specific facts in ex parte proceedings”). For recent *obiter dictum* in this Court, see *Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2005) (Newman, J., dissenting) (“Despite its broad power to grant or deny patents, the Patent and Trademark Office does not have the responsibility, or the authority, to depart from the law, or to make or change the policy embodied in the law, or to reinterpret the statute in a way that departs from congressional intention or judicial interpretation.”). Underlying the majority opinion in *Star Fruits* was the PTO’s unprecedented and unlegislated action of holding that a foreign sale of a plant having a foreign breeder’s rights registration, more than one year prior to the filing of a U.S. patent application, bars the patentability of it under 35 U.S.C. § 102(b). Judge Newman went on to say that “[w]hen an agency unilaterally makes a major and far-reaching change in law, the entire administrative process need not be forced to proceed on the incorrect law, a process that may consume years, in order to challenge the change in law.”

**POINT I**  
**The Judgment Of The District Court Should**  
**Be Affirmed Because The Presumption Of Patentably**  
**Indistinct Claims And Onerous Obligations Imposed On**  
**Applicants By The Overlap Rules Are Unwarranted And Unjustifiable**

Final Rule 1.78(f)(2)(i) – (iii) (the “Overlap Rules”) requires an inventor who files multiple, commonly-assigned patent applications on the same day (or within two months) that include common inventors and overlapping disclosures, to explain why the claims in the applications are patentably distinct, or else submit a terminal disclaimer and explain to the satisfaction of the PTO why two or more pending applications should be maintained. The Overlap Rules impose substantial new burdens on applicants who have followed the practice that—until now—has been favored by the PTO: initially filing claims to such inventions in separate patent applications. 37 C.F.R. § 1.141(a). Compliance is coerced by the threat of an administrative presumption that claims in these applications are not patentably distinct, and may be rejected on “obviousness-type” double patenting grounds that if not overcome by the applicant would require a terminal disclaimer. If the PTO is not satisfied, then the inventor would be required to eliminate the patentably indistinct claims from all but one of the applications. This kind of rulemaking alters the rights of patent applicants as it imposes a burden so high that it would undermine existing rights provided for by substantive patent law, including the underlying “one invention-one patent” principle of 35 U.S.C. § 101.

**A. The burden of complying with FR 1.78(f)(2)**

Rule 78(f)(2) would carry with it a presumption that claims in two applications are not patentably distinct—*i.e.*, that their subjects matter are mutually obvious—if four conditions are met:

- there is an overlap in any of their associated filing dates (including the dates of any foreign, international, or provisional filings from which priority is claimed). Rule 78(f)(2)(i)(A);
- there is an overlap between any two inventors. Rule 78(f)(2)(i)(B);
- they are commonly owned. Rule 78(f)(2)(i)(C); and
- they contain substantially overlapping disclosures. Rule 78(f)(2)(i)(D).

This presumption would arise automatically, and would have to be overcome within four months of the application filing date. Rule 78(f)(2)(iii)(A); 72 Fed. Reg. at 46783. Failure to overcome the presumption would result in claims being rejected on grounds of “double patenting”; patent applicants would have to take unduly elaborate and expensive precautions to ensure that patent rights are not inadvertently lost through non-compliance with these Overlap Rules.

To comply with Rule 78(f)(2), applicants would first have to identify which of their applications are at risk of inadvertent invalidity. The applicants would then need to determine if the identified applications have “substantially overlapping disclosures.” Rule 78(f)(2)(i)(D). The Rules defines “substantially overlapping disclosure” in terms that require interpretation by skilled patent practitioners: “Substantially overlapping disclosure exists if the other pending or patented nonprovisional application contains written support under the first paragraph of 35 U.S.C. § 112 for at least one claim in the nonprovisional application.” Rule 78(f)(2)(i)(D). The burden of “clearing” applications that have non-overlapping subjects matter is significant. As an example, if four applications have overlapping inventorships and filing dates, and if each of these applications includes five independent claims (as would be permitted even under FR 1.75(b)(1)-(5), an applicant could “clear” these applications only after making

sixty separate comparisons between independent claims and disclosures.<sup>20</sup> The burden of carrying out this task would grow disproportionately with the size of an organization: the likelihood that applications will be presumed patentably indistinct by mere coincidence greatly increases as the number of applications within an organization increases, and as the average number of inventors contributing to each application increases. The burden would fall not only on industry, but on large universities (and university systems) and research institutes as well.

For applications having substantially overlapping disclosures, the applicants would be required to explain why in a substantive and comprehensive way. “Merely explaining that some of the claims are patentably distinct would not be sufficient to rebut this presumption.” 72 Fed. Reg. at 46780. Using the PTO’s example of four applications with five claims each, the applicant would need to provide a substantive, comprehensive explanation for the presence of 150 pairs of claims<sup>21</sup> that otherwise will be presumed to be patentably indistinct.

The burden of complying with Rule 78(f)(2) would be particularly acute when adding new claims during the prosecution of a family of related applications. The ownership, inventorship, subject matter, and filing dates of such applications would almost inevitably trigger the presumption of patentably indistinct claims. Whenever any *new* claim is added to one of these applications,

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<sup>20</sup> Each of the five independent claims, in each of the four applications, is compared against three other disclosures, *i.e.*,  $5 \times 4 \times 3 = 60$ .

<sup>21</sup> There are six different ways to pair four applications (*i.e.*, 1&2, 2&3, 3&4, 4&1, 1&3, 2&4). Within each pair of applications, there are  $5 \times 5 = 25$  pairs of claims. Together,  $6 \times 25 = 150$ .

it must be accompanied by a justification of its existence with respect to every other claim in the application family.

**B. The administrative presumption of double patenting conflicts with the legitimacy of claiming related inventions in different applications**

35 U.S.C. § 101 states the “one invention-one patent” substantive law principle underlying the Patent Act (“[w]hoever invents . . . may obtain *a* patent”) (emphasis added). Consistent with § 101, the *Rules of Practice* authorize and encourage inventors to claim different inventions in different patent applications. 37 C.F.R. § 1.141(a) (“Two or more independent and distinct inventions may not be claimed in one national application . . .”). In advocating for the authority to promulgate Rule 1.78(f), the PTO does not oppose the description of multiple inventions in a single application. Further, 35 U.S.C. § 112, ¶ 1 requires applicants to provide “a written description of the invention, *and* of the manner and process of making *and* using it.” (emphasis added). Often, the “making” and the “using” of the invention are themselves separately patentable inventions, yet are required by statute to be described in a single application.

**C. FR 1.78(f)(2) abrogates the PTO’s statutory obligation to examine patent applications and provide reasoned rejections**

Rule 1.78(f)(2) enables the PTO to reject an application on “double patenting” grounds and avoid its statutory duty under 35 U.S.C. § 131 to examine applications for patentability.

The PTO is required by statute to examine applications to determine whether “the applicant is entitled to a patent under the law,” 35 U.S.C. § 131.<sup>22</sup> However, Rule 78(f)(2) would effectively relieve the PTO of that duty by creating a presumption that the applicant is *not* entitled to a patent, because the presumption of patentably indistinct claims is one of double patenting. *In re Longi*, 759 F.2d 887, 895-96 (Fed. Cir. 1985) (requiring the PTO to make out a “prima facie case of obviousness” when issuing a double-patenting rejection).

Indeed, the PTO itself admits that Rule 78(f)(2) was intended to shift the responsibility of examining for double patenting away from the PTO and onto the applicant:

Therefore, with the benefit of § 1.78(f)(2), double patenting issues could be resolved more expeditiously... thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection.

72 Fed. Reg. at 46780. More succinctly, the PTO views Rule 78(f)(2) as a means of “requiring the applicant to ferret out which claims are indistinct from each other.” 72 Fed. Reg. at 46815.

The PTO contends that its rulemaking authority includes “sett[ing] burdens of proof.” PTO Opp’n at 23. However, the only jurisprudence cited by the PTO

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<sup>22</sup> The Patent Act sets forth the PTO’s central role in the “processing of patent applications,” 35 U.S.C. § 2(b)(2)(C) and that of “granting and issuing of patents,” 35 U.S.C. § 2(a)(1);

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 a patent under the law, the Director shall issue a patent therefor.

35 U.S.C. § 131. If it is determined that a patent application should be rejected or objected to, the Director issues a rejection, 35 U.S.C. § 132(a) requires the Director to “notify the applicant thereof, stating the reasons for such rejection.”

in support of its contention does not stand for such a proposition. In *Stevens v. Tamai*, 366 F.3d 1325, 1333 (Fed. Cir. 2004), this Court noted in *obiter dicta* that the PTO can place the burden of providing priority on parties to an interference. 35 U.S.C. §§ 6, 102(g) and 135. But in that instance, it is the statute itself that sets the burden of proof, 35 U.S.C. § 102(g)(1) (noting that a later inventor is not entitled to a patent if, “during the course of an interference . . . another inventor involved therein *establishes*” his priority (emphasis added)).

Whereas the PTO is required by 35 U.S.C. §§ 131 and 132(a) to examine applications and to provide reasons for any claim rejections, Rule 78(f)(2) requires applicants to examine their own applications and provide reasons why claims should *not* be rejected. The PTO is statutorily required under 35 U.S.C. § 133 to give an applicant at least 30 days to respond to any rejection or other action, but the presumption of Rule 78(f)(2) arises automatically without notice to the applicant. Because Rule 78(f)(2) is “inconsistent with law” governing the PTO’s rulemaking authority under 35 U.S.C. § 2(b)(2), the judgment of the district court enjoining the promulgation of that rule should be affirmed. *See In re Weber*, 580 F.2d 455, 458-59 (C.C.P.A. 1978) (“[I]n drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.”).

**D. FR 1.78(f)(2) violates applicants’ statutory right of judicial review of claim rejections**

By characterizing double-patenting rejections as *procedural* in nature, FR 1.78(f)(2) deprives applicants of their statutory right of judicial review of PTO decisions affirming examiners’ double-patenting rejections. Specifically, in attempting to circumvent its duty to examine applications for claims to patentably

indistinct inventions, the PTO takes the position that “requiring the applicant to ferret out which claims are indistinct from each other” is merely “procedural in nature,” 72 Fed. Reg. at 46815. Although it labels Rule 78(f)(2) as a “procedural tool,” 72 Fed. Reg. at 46815, the PTO has made it clear that procedural failures will result in substantive rejections:

[W]hen an applicant files multiple applications that are substantially the same, the applicant is responsible for assisting the Office in resolving potential double patenting situations, rather than taking no action until faced with a double patenting rejection. Thus, if an Office action must include a double patenting rejection, it is because the applicant has not met his or her responsibility to resolve the double patenting situation.

72 Fed. Reg. at 46722. This derogates applicants’ statutory rights under 35 U.S.C. § 141 (direct appeal to the Federal Circuit on the record that was before the PTO Board of Patent Appeals and Interferences (“Board”)) and 35 U.S.C. § 145 (intermediate appeal on a *de novo* basis by civil action against the PTO) under which applicants can seek and obtain judicial consideration of claim rejections on a “substantial evidence” standard of review. Rule 78(f)(2) treats a double-patenting “situation” as the result of a *procedural* defect: the failure of an applicant to file a preemptive explanation under Rule 78(f)(2)(ii). The PTO’s refusal to issue a patent on procedural grounds can be challenged only by bringing a civil action under the Administrative Procedure Act, where the PTO’s decisions are reviewed under the more deferential “abuse of discretion” standard. *Star Fruits*, 393 F.3d at 1281.

Normally, patent applicants who are dissatisfied with examiners’ final rejections are entitled to several levels and routes of review under 35 U.S.C. §§ 134, 141 & 145. Applicants are entitled to *de novo* review of the legal bases for double-patenting rejections. As this Court has repeatedly held when

reviewing double-patenting rejections by the PTO, “Obviousness-type double patenting is a question of law reviewed *de novo* by this court.” *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993). Thus, contrary to law, a double-patenting rejection triggered by a presumption under Rule 78(f)(2) denies the applicant’s statutory right to *de novo* review on appeal. Instead, it sets a strict time limit within which the “patentably indistinct” presumption must be overcome. Rule 78(f)(2)(iii). The most draconian provision of this section requires the presumption to be overcome on the very day a new claim is added. Rule 78(f)(2)(iii)(C). “[I]f applicant subsequently files an amendment that adds a new claim after four months from the filing date of the application, applicant must rebut this presumption for such a claim *when applicant files the amendment*.” 72 Fed. Reg. at 46783 (emphasis added). By casting all double-patenting rejections as procedural matters, the PTO, in one fell swoop, sheds its own statutory duty to “reexamine” rejected applications and divests the Board and the courts of their statutory jurisdiction to review double-patenting rejections *de novo*. Because no agency—including the PTO—has the authority to enact rules that are contrary to law, the district court’s judgment permanently enjoining the PTO’s promulgation of Rule 78(f)(2) should be affirmed.

Also, after an initial rejection of an applicant’s claim, the applicant may “persis[t] in his claim for a patent,” even “without amendment,” and the statute requires that “the application shall be reexamined.” 35 U.S.C. § 132(a). If the claims are rejected again, the applicant may appeal to the Board. 35 U.S.C. § 134(a). If the applicant is unsuccessful before the Board, he may appeal directly to this Court under 35 U.S.C. § 141 or proceed by way of intermediate

judicial review in the form of a civil action against the PTO under 35 U.S.C. § 145.

In addition, controlling case law bars the PTO from rejecting (as opposed to objecting to) claims for procedural defects. Prior to the Final Rules, when “two or more applications filed by the same applicant contain conflicting claims [*i.e.*, patentably indistinct claims], elimination of such claims from all but one application may be required....” 37 C.F.R. 1.78(b). This Court’s predecessor held that 37 C.F.R. § 1.78(b) labeled as a procedural “requirement,” could not be used in place of a legally deficient double-patenting rejection:

In Rule 78(b), *supra*, the Commissioner has stated that he may “require” elimination of conflicting claims from all but one application of the same applicant. “Requirements” are not reviewable by the board or by this court unless they amount in fact to rejections.... [B]y refusing to permit further prosecution of the appealed claims in this application without the performance by appellant of an act wholly extrinsic to this application [the USPTO] has, in legal effect, rejected these claims finally.

*In re Mott*, 539 F.2d 1291, 1295-96 (C.C.P.A. 1976) (citations omitted); *see also In re Haas*, 486 F.2d 1053, 1056 (C.C.P.A. 1973) (holding that a requirement to withdraw claims was a “de facto rejection...made without statutory basis”). Thus, 37 C.F.R. § 1.78(b) cannot be the basis of a substantive double-patenting rejection.

**E. FR 1.78(f)(2) directly conflicts with 35 U.S.C. § 121**

Section 121 of the Patent Act was intended to remedy the injustice that results when the PTO reverses its position that claims in different applications are patentably distinct. FR 1.78(f)(2) frustrates both the intent and the literal requirements of § 121.

The PTO has long followed the practice of requiring patentably distinct claims to be divided into separate patent applications by issuing a “restriction requirement.” Prior to the Patent Act, such practice led to unjust results when the agency erred or changed its position on whether claims were patentably distinct. After requiring applications to be divided, the agency would sometimes reject the divided application on the grounds of double patenting. *In re Eisler*, 203 F.2d 726, 728 (C.C.P.A. 1953); *In re Seebach*, 88 F.2d 722, 723-24 (C.C.P.A. 1937) (affirming USPTO’s rejection for doubling patenting, while recognizing that the rejection “is tantamount to a decision that the requirement for division of the parent application was improper”).

To protect applicants against reversals of the agency’s determinations that claims are patentably distinct, Congress enacted 35 U.S.C. § 121. *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 360 (Fed. Cir. 1986) (Newman, J., concurring) (“[F]rom the practical viewpoint § 121 is particularly important when the restriction requirement is asserted to have been imposed in error.”). To create the protection, § 121 “effects a form of estoppel that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent.” *Id.* at 361.

Rule 78(f)(2) circumvents this statutory protection. In particular, Rule 78(f)(2), the presumption of patentably indistinct claims will inevitably apply to divisional applications, which share disclosures, filing dates, inventorship, and ownership with their respective patent applications. If the PTO follows its own existing rules, it will be required to presume that the claims of divisional applications are patentably indistinct from those of their parent applications—exactly the situation that § 121 was designed to prevent. Even if the PTO hesitates to impose a double-patenting rejection on the precise claims against

which the restriction requirement was applied, with each *new* claim added during prosecution of the divisional or parent application, the presumption of patentably indistinct claims arises anew, and it must be rebutted on the very date the new claim is submitted. Rule 78(f)(2)(iii)(C). If the rebuttal is not successful, then according to the Final Rules, the application would lose its status as a “divisional” and thus—in the eyes of the USPTO—lose the protection under § 121 altogether. *See* Rule 78(a)(2) (defining “divisional application”); *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348 n. 1 (Fed. Cir. 2004) (“[T]he question whether the requirements of section 121 have been satisfied is a question of law that we have addressed *de novo*”).

Under 35 U.S.C. § 121, the PTO *cannot* require applicant(s) in a divisional application to demonstrate that their claims are patentably distinct. Under the Final Rules, however, applicants in a divisional application *must* demonstrate that their claims are patentably distinct even to merit the protection of § 121. Rule 78(f)(2) defeats both the letter and the intent of § 121, and thus exceeds the scope of the PTO’s rulemaking authority. *See Chevron, U.S.A., Inc. v. Natural Resources Defense, Inc.*, 467 U.S. 837, 843 n. 9 (1984) (“The judiciary...must reject administrative constructions which are contrary to clear congressional intent.”).

## **POINT II**

### **The Judgment Of The District Court Should be Affirmed Because The Pre-Existing Requirements Of The PTO’s Disciplinary Rules Render The 2 + 1 Final Rules Unnecessary**

The PTO disciplinary rules offer a means of discouraging what the PTO has characterized as abusive continuing application and RCE filing practices.

Since long before the PTO's announcement of its Final Rules, the *Rules of Practice* have contained provisions in 37 C.F.R. § 10.18 and § 10.23 which read in pertinent part as follows:

**§ 10.18 Signature and certificate for correspondence filed in the Patent and Trademark Office.**

\* \* \*

(b) by presenting to the Office (whether by signing, filing, submitting, or later advocating) any paper, the party presenting such paper, whether a practitioner or non-practitioner, is certifying that –

\* \* \*

(2) To the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, that –

(i) The paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or needless increase in the cost of prosecution before the Office;

(ii) The claims and other legal contentions therein are warranted by existing law . . .

\* \* \*

(c) Violations of . . . any of paragraphs (b)(2) . . . of this section are, after notice and reasonable opportunity to respond, subject to such sanctions as deemed appropriate by the Commissioner, or the Commissioner's designee, which may include, but are not limited to, any combination of –

\* \* \*

(2) Returning papers;

(3) Precluding a party from filing a paper, or presenting or contesting an issue;

(4) Imposing a monetary sanction;

(5) Requiring a terminal disclaimer for the period of the delay; or

(6) Terminating the proceedings in the [PTO].

(d) Any practitioner violating the provisions of this section may also be subject to disciplinary action. *See* § 10.23(c).

### § 10.23 Misconduct.

\* \* \*

(b) A practitioner shall not:

(1) Violate a Disciplinary Rule.

\* \* \*

(c) Conduct which constitutes a violation of paragraph[s] . . . (b) of this section includes, but is not limited to:

\* \* \*

(15) Signing a paper filed in the Office in violation of the provisions of § 10.18 . . . .

During the pendency of the present appeal, the PTO reinforced its adherence to the administrative policy expressed in 37 C.F.R. § 10.18 by re-promulgating essentially the same rule now set forth in 37 C.F.R. § 11.18(b) and (c).<sup>23</sup> It would be difficult to imagine a more effective means for preventing the kind of abusive continuation practice alleged by the PTO in justifying its Final Rules. Nevertheless, the public record of the PTO's rulemaking deliberations<sup>24</sup> nowhere indicates that any serious consideration was given by the PTO to utilizing these disciplinary rules as an alternative to the Final Rules, thus rendering the latter arbitrary on their face and hence *ultra vires*.

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<sup>23</sup> *Changes to Representation of Others Before the United States Patent and Trademark Office*; Final Rule, 73 Fed. Reg. 47650-47704 (Aug. 14, 2008).

<sup>24</sup> 71 Fed. Reg. 48-60 (Jan. 3, 2006), 71 Fed. Reg. 61-69 (Jan. 3, 2006), and 72 Fed. Reg. 46716- 46843 (Aug. 21, 2007). During the course of the proceedings in the District Court, plaintiffs were denied access to the PTO's non-public rulemaking proceedings on the grounds of "deliberative process privilege."

**POINT III**  
**The Judgment Of The District Court Should Be Affirmed**  
**Because The 2 + 1 Rules Contravene Settled Law**

The NYIPLA endorses the positions expressed by plaintiffs-appellees on this issue.

Final Rules 1.78(d)(1)(i) - (vi) and 1.114(f) - (h) (the “2 + 1 Rules”) impose unreasonable conditions that would effectively limit the number of continuing applications and requests for continued examinations (RCEs”) that an inventor may file. These conditions require that an applicant’s third or subsequent continuing application filed under 37 C.F.R. § 1.53(b), whether in the form of a continuation or a continuation-in-part, or an applicant’s second or subsequent RCE, be accompanied by a “showing” as to why such filings are necessary. 72 Fed. Reg. 46838; 46841. Such rulemaking is contrary to clear and unambiguous statutory mandates and well-established jurisprudence.

**A. The PTO’s assumption of authority to limit the number of continuing applications claiming priority to a common antecedent application under 35 U.S.C. § 120 is contrary to binding precedent**

The Patent Act imposes no restrictions on the number of continuing applications that an inventor may file, nor does it give the PTO the authority to limit the number of such applications by restricting the number of times the benefit of priority can be claimed in a chain of copending applications. In particular, 35 U.S.C. § 120 provides, in pertinent part, the following:

*“[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor...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....”*

(Emphasis added). In interpreting § 120, the Court of Customs and Patent Appeals held that there is *no* defensible justification under that statute for limiting by agency decree the number of prior applications through which a chain of copendencies may be traced to obtain the benefit of priority to the filing date of the earliest application. *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968). Even long before the enactment of the Patent Act, this was recognized as the law. *Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863) (patent applicant entitled to file multiple continuations provided statutory conditions are met).

The PTO admitted in its notice of proposed rulemaking that it “is aware of case law [e.g., *In re Henriksen*] which suggests that the Office has no authority to place an absolute limit on the number of copending continuing applications originating from an original application.”<sup>25</sup> In trying to sidestep this controlling precedent, the PTO asserts that Rule 78(d)(1)(i) – (vi) does not limit the number of continuing applications that can be filed, but rather, that it merely seeks to require an adequate “showing” be made to justify them. The agency has gone on record as stating that it merely wants inventors to show that the third and all ensuing applications in the chain of applications are necessary to advance prosecution.<sup>26</sup> Under the Final Rule, if an applicant fails to satisfy the “showing” requirement, the examiner must refuse to enter (or delete if present) any specific reference to a prior-filed application. Rule 78(d)(1)(vi). If such a “showing” is not made to the examiner’s satisfaction, then the right of priority to the filing date of an antecedent application in a chain of copending cases—and hence the value of the subject matter claimed therein—would be effectively compromised if not destroyed.

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<sup>25</sup> 71 Fed. Reg. 50, right-hand column, third full paragraph.

<sup>26</sup> 71 Fed. Reg. 50, right-hand column, second full paragraph.

The PTO's "showing" argument fails because contrary to the agency's assertion, the *effect* of the Final Rule would be to impermissibly limit the number of copending continuing applications originating from an initial application. In practice, an inventor would rarely be able to make a "showing" satisfactory to the examiner that "the amendment, argument, or evidence presented could not have been previously submitted." This would result in innumerable rejections as an examiner could always make the argument that the evidence *could have been* submitted earlier.

The following example illustrates the potential § 102(b) bar that could arise. Assume that an inventor files an initial application on November 5, 2009, and that the application matured into a patent on December 12, 2014. Before the patent is issued, the applicant files a continuing application on December 11, 2014, and continued to file copending applications thereafter until a third continuation application is filed on September 15, 2017. Under the Final Rule, if the inventor failed to make the requisite "showing" for the third continuing application, then the PTO could deny the applicant's claim to priority in such a application, and the antecedent patent could be cited by the PTO or by a future adversary in a litigation as a bar under 35 U.S.C. § 102(b) to the granting of a patent on the third continuing application.<sup>27</sup>

**B. Legislation limiting the number of sequential copending continuing applications that can be filed from an initial application has not been forthcoming**

A recent law review article expresses clear disapproval of continuing application practice, yet states unequivocally that "[a]bolishing patent

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<sup>27</sup> The publication of the first application could also be used under 35 U.S.C. § 103 to render obvious the claims in the third continuation-in-part application that are directed to the newly-added subject matter.

continuations would require legislative action”<sup>28</sup> and that “[l]imiting the number of continuations that can be filed may require an act of Congress,”<sup>29</sup> citing *Henriksen*.

Since 2005, Congress has repeatedly considered whether to delegate substantive rulemaking authority to the PTO and has declined to do so each time. In June 2005, the “Patent Reform Act of 2005” was introduced in the House.<sup>30</sup> Among its many controversial features was a provision amending § 120 that would have given the PTO the authority to limit the number of continuing applications that an applicant could file.<sup>31</sup> In July 2005, an “Amendment in the Nature of a Substitute to H.R. 2795” was introduced. Unlike H.R. 2795 *as initially presented*, the Amendment had *no* provision in it that would have authorized the PTO to limit the number of continuing applications that an applicant may file. Inclusion of a continuation-limiting provision in H.R. 2795, but not in the subsequent amendment bill, attests to Congress’s skepticism as to whether such a provision would be beneficial to our patent system. In April 2006, a bill was introduced entitled “Patents Depend on Quality Act of 2006, H.R. 5096, 109th Cong. (2006)” that likewise didn’t include any provision limiting the number of continuing applications that an applicant may file.

In light of unequivocal statutory authority and judicial interpretations of the same, the PTO’s proper recourse in this case would have been to lobby

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<sup>28</sup> Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 105 (2004).

<sup>29</sup> *Id.* at 107.

<sup>30</sup> H.R. 2795, 109th Cong. § 8 (June 1, 2005).

<sup>31</sup> SEC. 8, CONTINUATION APPLICATIONS, subsection 123, Limitations on Continuation Applications, provides that “[t]he Director may by regulation limit the circumstances under which an application for patent...may be entitled to the benefit under section 120 of the filing date of a prior-filed application.”

Congress for legislation giving the agency a clear, unambiguous statutory mandate to limit the number of continuations that an applicant can file. Instead, the PTO assumed a substantive rulemaking role by promulgating the Final Rules without a clear Congressional mandate. Upholding these Final Rules while simultaneously interpreting 35 U.S.C. § 120 to bar the PTO from limiting the number of continuation applications that an inventor may pursue would result in inconsistent rulings that would seriously weaken our patent system.

#### **POINT IV**

##### **The Judgment Of The District Court Should Be Affirmed Because The 5/25 Claim Limit And ESD Rules Contravene Settled Law**

The NYIPLA endorses the positions expressed by plaintiff-appellees on this issue.

Final Rule 1.75(b)(1) - (5) (the “5/25 Rule”) would allow an inventor to file a maximum total of twenty-five claims, including five independent claims in any given application. If the applicant deems it necessary to have more than twenty-five claims examined initially, then a so-called Examination Support Document (“ESD”) would be required. The ESD would have to identify all of the features in the claims that are disclosed by references uncovered in a broad search of the prior art that the applicant must carry out in the first instance, and explain in detailed how the claims are patentable over the references that have been cited in accordance with 37 C.F.R. § 1.111(b) and (c).

Imposing such a requirement not only affects the substantive rights of patent applicants, it is also unreasonable and unfair because it would require the applicant to search for, review, analyze, and characterize the prior art in assessing the patentability of the claimed invention—a statutory task that falls exclusively

upon the examiner under 37 C.F.R. § 1.104,<sup>32</sup> a rule that administers the statutory requirement under 35 U.S.C. § 131 that the PTO assess the patentability of the claimed invention as part of the examination process. The impropriety of requiring ESDs is brought home by the fact that the fees associated with the filing of an application include money paid by the applicant for the examiner's search for prior art to be applied against the claimed invention. Moreover, such fees include a fee for presenting claims in excess of three independent and twenty total claims, such that the PTO is already receiving increased revenue from applicants who submit additional claims for examination. By also having to review and characterize the prior art, the applicant is in effect paying for the privilege of wearing two hats—that of the applicant and that of an examiner. Shifting the responsibility for examining patent applications from the PTO to the applicant would fundamentally and unlawfully alter the United States patent system and its laws. Contrary to the PTO's assertion in its brief that an ESD would serve as a “launch pad” for additional searching within the PTO, examiners (whose performance evaluations are determined in large part by the number of case “disposals” they achieve in each calendar quarter), will be inclined to rely unduly, if not entirely, on what an applicant submits by way of prior art. Congress has, in no uncertain terms made it the responsibility of the examiner to examine the application and to search for and analyze the prior art with or without input from the applicant. Shifting the obligation to do so from

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<sup>32</sup> 37 C.F.R. § 1.104 Nature of examination.... (a) Examiner's action.... (1) On taking up an application for examination..., the *examiner shall* make a thorough study thereof and *shall* make a thorough investigation of the available prior art relating to the subject matter of the claimed invention (emphasis added).

the examiner to the applicant represents a fundamental and inappropriate shift from our current examination system to a registration system.

### CONCLUSION

For all of the reasons herein set forth, *amicus curiae* NYIPLA respectfully urges affirmance of the district court's judgment permanently enjoining the PTO from implementing the Final Rules.

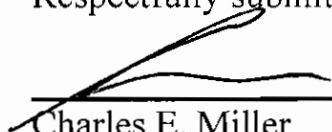
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**DECLARATION/CERTIFICATE OF SERVICE AND FILING**


Pursuant to Fed. R. App. P. 25(b), (c), and (d), I, Charles E. Miller, being duly sworn, depose and certify that I am not a party to the action, I am over 18 years of age, and have a place of business at Dickstein Shapiro LLP, 1177 Avenue of the Americas, New York, NY 10036-2714, and that on October 3, 2008 I served the within

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Dated: October 3, 2008



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