

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

TRANTAFYLLOS TAFAS,

Plaintiff,

- against -

JON. W. DUDAS, et al., et al.,

Defendants.

1:07cv846 JCC/TRJ
Judge Cacheris

SMITHKLINE BEECHAM CORPORATION, et al.,

Plaintiff,

- against -

JON. W. DUDAS, et al., et al.,

Defendants.

1:07cv1008 (JCC/TRJ)
Judge Cacheris

**BRIEF OF *AMICUS CURIAE* CFPH, LLC
IN SUPPORT OF PLAINTIFFS' SUMMARY JUDGMENT MOTIONS**

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TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
A. STATEMENT OF FACTS	2
1. The Presumption of Patentable Indistinctness	3
2. Requirements to Prove Patentability.....	6
3. Limits on Continuation Applications and RCEs.....	8
II. ARGUMENT	10
A. The Final Rules Illegally Impose Substantive, Not Procedural, Requirements	10
1. The Presumption of Patentable Indistinctness is Substantive.....	11
2. The Requirements to Prove Patentability Are Substantive.....	16
3. The Limits on Continuation Applications Are Substantive.....	17
B. The Final Rules Illegally Shift Burdens of Proof.	18

TABLE OF AUTHORITIES

	<u>Page</u>
Cases	
<i>Air Transport Assn. of Am. v. Dept. of Transportation</i> , 900 F.2d 369 (D.C. Cir. 1990).....	13, 15
<i>Alabama Power Co. v. Costle</i> , 636 F.2d 323 (D.C. Cir. 1979).....	20
<i>Alcaraz v. Block</i> , 746 F.2d 593 (D.C. Cir. 1984).....	11
<i>American Airlines, Inc. v. CAB</i> , 359 F.2d 624 (D.C. Cir. 1966) (en banc).....	22
<i>American Dredging Co. v. Miller</i> , 510 U.S. 443 (1994).....	14
<i>American Hoist & Derrick Co. v. Sowa & Sons, Inc.</i> , 725 F.2d 1350 (Fed. Cir. 1984).....	8
<i>American Hospital Ass’n. v. Bowen</i> , 834 F.2d 1037 (D.C. Cir. 1987).....	passim
<i>American Mining Congress v. Mine Safety & Health Admin.</i> , 995 F.2d 1106 (D.C. Cir. 1993).....	13, 15
<i>Animal Legal Defense Fund v. Quigg</i> , 932 F.2d 920 (Fed. Cir. 1991).....	11, 12, 13, 14
<i>Bachow Communs., Inc. v. Federal Communications Comm’n.</i> , 237 F.3d 683 (D.C. Cir. 2001).....	13, 14
<i>Batterton v. Marshall</i> , 648 F.2d 694 (D.C. Cir. 1980).....	12, 13, 15
<i>Community Nutrition Inst. v. Young</i> , 818 F.2d 943 (D.C. Cir. 1987).....	8
<i>Dickinson v. Zurko</i> , 527 U.S. 150 (1999).....	11
<i>Director, Office of Workers Compensation Programs v. Greenwich Collieries</i> , 512 U.S. 267, 271 (1994).....	14, 19, 22
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	4

TABLE OF AUTHORITIES (con't)

	<u>Page</u>
<i>Heckler v. Campbell</i> , 461 U.S. 458, 46 (1983).....	22
<i>Hoechst Aktiengesellschaft v. Quigg</i> , 917 F.2d 522 (Fed. Cir. 1990)	12
<i>Hyatt v. Dudas</i> , 492 F.3d 1365 (Fed. Cir. 2007)	8
<i>In re Alton</i> , 76 F.3d 1168 (Fed. Cir. 1996)	5, 8
<i>In re Berg</i> , 140 F.3d 1428 (Fed. Cir. 1998)	3, 4
<i>In re Bogese</i> , 303 F.3d 1362 n.6 (Fed. Cir. 2002)	10, 18
<i>In re Braithwaite</i> , 379 F.2d 594 (C.C.P.A. 1967)	18
<i>In re Epstein</i> , 32 F.3d 1559 (Fed. Cir. 1994)	4
<i>In re Glaug</i> , 283 F.3d 1335 (Fed. Cir. 2002)	5
<i>In re Griswold</i> , 365 F.2d 834 n.5 (C.C.P.A. 1966)	18
<i>In re Henrickson</i> , 399 F.2d 253 (C.C.P.A. 1968)	20
<i>In re Hogan</i> , 559 F.2d 595 (C.C.P.A. 1977)	20
<i>In re Lee</i> , 277 F.3d 1338 (Fed. Cir. 2002)	23
<i>In re Longi</i> , 759 F.2d 887 (Fed. Cir. 1985)	4
<i>In re Oetiker</i> , 977 F.2d 1443 (Fed. Cir. 1992)	5
<i>In re Piasecki</i> , 745 F.2d 1468 (Fed. Cir. 1984)	5

TABLE OF AUTHORITIES (con't)

	<u>Page</u>
<i>In re Rinehart</i> , 531 F.2d 1048 (C.C.P.A. 1976)	5
<i>In re Robeson</i> , 331 F.2d 610 (C.C.P.A. 1964)	3
<i>In re Rouffet</i> , 149 F.3d 1350 (Fed. Cir. 1998)	4
<i>In re Siu</i> , 222 F.2d 267 (C.C.P.A. 1953)	3
<i>In re Van Ornem</i> , 686 F.2d 937 (C.C. P.A. 1982)	17, 18
<i>In re Warner</i> , 379 F.2d 1011 (C.C.P.A. 1967)	4, 5
<i>In re Zickendraht</i> , 319 F.2d 225 (C.C.P.A. 1963)	18
<i>Inova Alexandria Hospital v. Shalala</i> , 244 F.3d 342 (4 th Cir. 2001)	14
<i>Jerri's Ceramic Arts, Inc. v. Consumer Product Safety Commission</i> , 874 F.2d 205 (4 th Cir. 1989).....	11, 20
<i>KSR International Co. v. Teleflex, Inc.</i> , 127 S.Ct. 1727 (2007).....	4
<i>Lefevre v. Secretary, Dept. of Vet. Aff.</i> , 66 F.3d 1191 (Fed. Cir. 1995)	passim
<i>J.E.M. Broad Co. v. Federal Communications Comm'n</i> , 22 F.3d 320 (D.C. Cir. 1994).....	14
<i>Mazzari v. Rogan</i> , 323 F.3d 1000 (Fed. Cir. 2003)	11
<i>McLouth Steel Corp. v. Thomas</i> , 838 F.2d 1317 (D.C. Cir. 1988).....	8, 21
<i>Merck & Co. v. Kessler</i> , 80 F.3d 1543 (Fed. Cir. 1996)	12
<i>Motor Vehicle Mfrs. Ass'n v. StateFarm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	23

TABLE OF AUTHORITIES (con't)

	<u>Page</u>
<i>Pacific Gas & Electric Co. v. Federal Power Commn.</i> , 506 F.2d 33 n.14 (D.C. Cir. 1974).....	11, 12, 13, 15
<i>Paralyzed Vets. of Am. v. Secretary of Veterans Affairs</i> 308 F.3d 1262, 1266 (Fed. Cir. 2002).....	11, 14
<i>Paralyzed Vets. of Am. v. West</i> , 138 F.3d 1434 (Fed. Cir. 1998)	11, 14
<i>RSM Inc. v. Buckles</i> , 254 F.3d 61 (4 th Cir. 2001)	12
<i>Star Fruits S.N.C. v. United States</i> , 393 F.3d 1277 (Fed. Cir. 2005).....	19
<i>Stevens v. Tama</i> , 366 F.3d 1325 (Fed. Cir. 2004)	16, 17
<i>Texaco, Inc. v. Federal Power Commn.</i> , 412 F.2d 740 (3d Cir. 1969)	15

Statutes

35 U.S.C. § 101.....	3
35 U.S.C. § 102.....	3, 15
35 U.S.C. § 103.....	3
35 U.S.C. § 120.....	16
35 U.S.C. § 131.....	11
35 U.S.C. § 132.....	11
35 U.S.C. § 2.....	10, 11, 13
35 U.S.C. § 363.....	14
35 U.S.C. § 371.....	14
35 U.S.C. § 372.....	13, 14
35 U.S.C. § 6.....	10
35 U.S.C. §135.....	3

TABLE OF AUTHORITIES (con't)

	<u>Page</u>
37 CFR § 1.105.....	15, 17
37 CFR § 1.109 (2006).....	3
37 CFR § 1.183.....	17
37 CFR § 1.56.....	7
37 CFR § 1.633.....	13
37 CFR § 1.647.....	13
37 CFR § 10.18.....	8
37 CFR § 1.637.....	13
37 CFR 1.321 (2006).....	2
5 U.S.C. § 553.....	9, 11, 17
5 U.S.C. § 556.....	18
5 U.S.C. § 706.....	18

Other Authorities

Manual of Patent Examining Procedure § 804 (8 th ed. 5 th rev. 2006).....	3
---	---

Rules

71 Fed. Reg. 48 (Jan. 3, 2006).....	5, 7, 9
72 Fed. Reg. 46,715 (Aug. 21, 2007).....	passim
New Rule 1.105.....	7
New Rule 1.265.....	6, 15, 16, 17
New Rules § 1.183.....	8, 9
New Rules 1.114.....	8
New Rules 1.78.....	passim

TABLE OF AUTHORITIES (con't)

	<u>Page</u>
Treatises	
2-5 <i>Chisum on Patents</i> § 5.06.....	5
3A-9 Donald S. Chisum, <i>Chisum on Patents</i> § 9.03 (Lexis-Nexis 2007)	3
6-19 <i>Chisum on Patents</i> § 19.03	7

I. INTRODUCTION

CFPH, LLC (Cantor Fitzgerald Patent Holdings, “CFPH”) submits this brief amicus curiae to assist the Court in evaluating motions for summary judgment to determine whether the U.S. Patent and Trademark Office (“PTO”) exceeded its legal authority in promulgating the rules at issue.¹ The Final Rules substantively change the manner in which the PTO would evaluate patentability, in ways that would dramatically limit and delay the ability of CFPH, Cantor Fitzgerald, L.P. and their affiliates (collectively “Cantor”) to obtain patents, limit the duration of the many patents that Cantor would nevertheless obtain, and increase the costs of obtaining those patents. These changes are illegal, as the PTO has not been delegated substantive rulemaking authority by the Congress and as the PTO may not by rulemaking alter the statutory burdens of proof regarding patentability and thus prejudice the patentability issue.

Cantor is a global financial services provider and recognized leader in the specialized areas of equity and fixed income capital markets, which also operates in investment banking, merchant banking, asset management, clearing and market data services, and energy emissions.² Cantor invests substantial financial and human resources in developing important new technologies and in seeking patent protection for them.³ Cantor (and many other entities) would be dramatically and adversely affected by the Final Rules if they were allowed to go into effect.⁴ Cantor provided extensive comments on the proposed rules that were published by the PTO, explaining why the proposed rules were unauthorized substantive rules, how they would illegally shift burdens of proof, that they lacked evidentiary support and rational justification, and many

¹ See 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. 46,715 (Aug. 21, 2007) (to be codified at 37 CFR Part 1) (“the Final Rules”).

² See Declaration of Dean Alderucci (“Alderucci Decl.”), attached as Exhibit 1, ¶ 10.

³ See *id.* at ¶ 11.

other legal failures.⁵ Cantor addresses below the first two of these issues, and why the Final Rules like the earlier proposals are illegal.

A. STATEMENT OF FACTS

The Final Rules adopt three categories of significant substantive changes to the existing requirements for prosecuting and examining patent applications. These are: (1) a presumption that at least one claim in an application is not patentably distinct from claims in other applications or patents having the same effective filing date, common inventors and owners, and substantially overlapping disclosures (“**presumption of patentable indistinctness**”), which triggers a requirement for the applicant either to rebut the presumption by proving that all claims are patentably distinct or to file a terminal disclaimer that restricts patent term and requires continued common ownership⁶; (2) requirements for applicants to search for prior art and to file an Examination Support Document (“ESD”) providing detailed explanations of why the claims are patentable and have written description support, whenever an application includes more than five independent and twenty-five total claims (“**requirements to prove patentability**”)⁷; and (3) limits to filing of more than two continuing applications and one request for continued examination (“RCE”), unless a petition is granted based on establishing that the new claim (or claim amendment), new argument, or new evidence could not have been submitted during the prosecution of earlier-filed applications (“**limits on continuation applications and RCEs**”).⁸

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⁴ See *id.* at ¶¶ 12-30.

⁵ See Comments of Dean Alderucci (“Cantor Comments”), Attachment A to Alderucci Decl.

⁶ New Rules 1.78(f)(2)(i)&(ii). See 37 CFR 1.321(c) (2006). All citations are to Title 37 of the CFR. The Final Rules appear at 72 Fed. Reg. 46,836-40.

⁷ New Rules 1.75(b)(1) and 1.265(a)(1),(4)&(5).

⁸ New Rules 1.78(d)(1)(i)-(v)&(vi) and 1.114(f)&(g).

1. The Presumption of Patentable Indistinctness

A patent claim may be patentably indistinct from claims in another application or issued patent if it describes the same invention⁹ or if it describes a sufficiently similar invention that would not be patentable in light of the other claims.¹⁰ The judicial doctrine of nonstatutory double patenting was developed to prevent patent holders from effectively extending the duration of the first patent to obvious variants of the invention, and to protect competitors against harassing duplicative litigation by assuring common ownership of patentably indistinct claims.¹¹ Nonstatutory double-patenting rejections must be made by the PTO whenever it determines that the claims are not patentably distinct from claims in a commonly owned application.¹²

Under the prior rules, nonstatutory double patenting rejections could not be made without an adjudication by the PTO that the *claims* in different applications were obvious (or otherwise unpatentable) in light of each other, which requires comparison of the actual claims.¹³ The PTO bore the burden of establishing a prima-facie case of unpatentability.¹⁴ Unless a prima facie case

⁹ This is referred to as statutory double patenting, and is prohibited under 35 U.S.C. § 101 (which permits inventors to obtain “a” patent for an invention).

¹⁰ This is referred to as nonstatutory double patenting, and is typically found where the later claim would be obvious under 35 U.S.C. § 103 in light of the earlier claims; hence it is often referred to as obviousness-type double patenting. *See, e.g., In re Vogel*, 422 F.2d 438, 441-42 (C.C.P.A. 1970).

¹¹ *See, e.g., In re Berg*, 140 F.3d 1428, 1431-35 (Fed. Cir. 1998); *In re Vogel*, 422 F.2d at 442; *In re Robeson*, 331 F.2d 610, 615 (C.C.P.A. 1964); *In re Siu*, 222 F.2d 267, 269-70 (C.C.P.A. 1953). *See generally* 3A-9 Donald S. Chisum, *Chisum on Patents* § 9.03[2][b]&[3] (Lexis-Nexis 2007) (“*Chisum on Patents*”) (discussing obviousness tests for patentable distinctness); *id.* § 9.04[2] (discussing harassment concerns underlying double patenting rejections and how they may be obviated by common ownership terminal disclaimers).

¹² *See* 37 CFR § 1.109(a) (2006). Examiners are instructed to make these rejections provisional to permit applicants to file a terminal disclaimer. *See* Manual of Patent Examining Procedure (“MPEP”) § 804, at 800-17 (8th ed. 5th rev. 2006). Absent common ownership, the PTO may declare an interference (a priority contest) under 35 U.S.C. § 135.

¹³ *See, e.g., Chisum on Patents* § 9.03[1][a].

¹⁴ *See, e.g., In re Longi*, 759 F.2d 887, 895-96 (Fed. Cir. 1985). *See also* MPEP, § 804, at 800-19 & 800-21 (examiners are instructed to determine obviousness-type double patenting using analysis that parallels the approach to obviousness rejections under 35 U.S.C. § 103(a)); *In re Berg*, 140 F.3d at 1431-35 (describing two tests for making obviousness-type double patenting

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had been established, applicants were entitled by the Patent Act to have their claims issue,¹⁵ without the need to limit duration or to restrict alienation through terminal disclaimers.

Under new Rule 1.78(f)(2)(i), the PTO has done away with any requirement for the PTO to determine that the claims are patentably indistinct. The new Rule simply adopts a legal presumption that entirely prejudices the issue, for applications having “substantially overlapping disclosures,” without ever comparing the language of the actual claims or evaluating them for obviousness or other unpatentability.¹⁶ Given the presumption, the PTO no longer must establish a prima-facie case. The new Rule thus shifts to the applicant the burden of proving the negative that *all* of the claims in the applications are patentably distinct.¹⁷

Rule 1.78(f)(2)(i) does not specify how such a rebuttal is to be achieved if the disclosures substantially overlap. The Final Rules do not specify the facts on which the presumption is purportedly based,¹⁸ and thus the only conclusive means of rebutting the new presumption would be to supply evidence and argument to favorably resolve *any and all possible evidentiary*

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rejections). Obviousness is decided under the complex and fact-sensitive analysis of *Graham v. John Deere Co.*, 383 U.S. 1 (1966), as further elaborated in *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007), but is a question of law, *see Graham*, 383 U.S. at 18.

¹⁵ *See, e.g., In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967) (“the precise language of 35 U.S.C. § 102 that ‘(a) person shall be entitled to a patent unless,’ concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office”); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (“In the absence of a proper *prima facie* case of obviousness, an applicant ... is entitled to a patent”); *In re Epstein*, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) (unlike the normal rule that an applicant seeking government-issued property “bears the burden of establishing entitlement to that grant,” for patents “the rule is that the burden of persuasion is on the PTO to show why the applicant is not entitled to a patent”).

¹⁶ *See* 72 Fed. Reg. at 46,783 (acknowledging comment that overlapping disclosures should not create a *prima facie* case of double patenting, which requires comparison of claims).

¹⁷ *See, e.g.,* 72 Fed. Reg. at 46,785 (requiring for rebuttal that applicants “point[] to unique claim element(s) ... that patentably distinguish[] them from the claims ... that gave rise to the § 1.78(f)(2) presumption”); *id.* (seeking to deny “that the applicant prove a negative,” because the applicant may identify the claim elements that patentably distinguish the claims).

¹⁸ There is *no* evidentiary basis in the record of the Final Rules to support a factual presumption leading from the fact of substantially overlapping disclosures to the legal conclusion of double patenting. As Cantor noted in its comments on the proposed rule, the PTO did not perform *any* analysis of the existence of double patenting in multiple applications, raising additional legal

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disputes (and logical inferences arising therefrom) that might support *the PTO's* burdens of production and persuasion on nonstatutory double patenting for *all* of the claims on all possible grounds of unpatentability. In contrast, when an applicant seeks to rebut a PTO rejection establishing a prima-facie case of obviousness, it only needs to supply sufficient evidence to challenge the specific prima-facie case made by the PTO, and then the PTO must reevaluate the entire record while continuing to bear the burden of persuasion (under the preponderance of evidence standard) in regard to potentially conflicting facts and their inferences.¹⁹

The PTO has effectively admitted that the Final Rules shift its burdens of proof, confirming this result in efforts to deny it.²⁰ The Final Rules are expressly based on the view that applicants are required to assist the PTO.²¹ Under the Final Rules, Cantor would now be found by the PTO to have patentably indistinct claims, even if rebuttal is attempted, and Cantor

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concerns. *See* Cantor Comments. The Final Rules provide no adequate response.

¹⁹ *See, e.g., In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002); *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1471-74 (Fed. Cir. 1984); *Warner*, 379 F.2d at 1017. *See also In re Alton*, 76 F.3d 1168, 1174-76 (Fed. Cir. 1996) (the PTO must provide adequate grounds for rejecting an applicant's rebuttal); *In re Rinehart*, 531 F.2d 1048, 1052 (C.C.P.A. 1976) (a prima facie case is a legal conclusion, not a fact, and when a prima-facie case is rebutted with new evidence "the decision-maker must start over"). *See generally* 2-5 *Chisum on Patents* § 5.06 (discussing the PTO's burden of a prima-facie case of obviousness).

²⁰ *See, e.g.,* 72 Fed. Reg. at 46,783 (incoherently stating that the "rebuttable presumption does not equate to a *prima facie* case of patentably indistinct claims[, because a]n applicant may rebut the presumption"); 72 Fed. Reg. at 46,815 (arguing that the rebuttable presumption of new Rule 1.78(f)(2)(i) is merely a procedural tool and "is not a merits determination of patentability," even though the PTO may rely on the rule to require a rebuttal or a terminal disclaimer). Nor do the Final Rules adequately explain how the presumption of patentable indistinctness "is not akin to a presumption of obviousness," how "the ultimate determination of double patenting" "rests" or "remain[s]" "with the Office" if it can rely solely on the new presumption, or how "the rebuttable presumption is not a merits determination of patentability" in the absence of a successful rebuttal. *Id.* at 46,780, 46,782, 46,783.

²¹ *See, e.g.,* 72 Fed. Reg. at 46,736 (applicants are "responsible for assisting the Office in resolving potential double patenting situations, rather than taking no action until faced with a double patenting rejection"); *id.* at 46,772 (same). *Cf.* Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 55 (Jan. 3, 2006) (applicants' responsibilities relate to filing terminal disclaimers once double patenting has been shown by the presumption).

then would lose either those claims or patent term.²² Cantor could not avoid filing multiple applications with distinct claims to avoid triggering the presumption (unless it foregoes needed patent protection significantly affecting Cantor's investments and finances), as separate applications are authorized by statute and required by the PTO's own rules.²³ Cantor also would bear much higher costs of prosecuting these claims and of filing terminal disclaimers.²⁴

2. Requirements to Prove Patentability

Under new Rules 1.75 (b)(1) and 1.265(a)(1), (4) & (5), applicants must now file ESDs that require them: (i) to search the prior art to develop potential evidence of unpatentability to be used against them during prosecution²⁵; (ii) to shoulder the burdens of proof on issues regarding patentability over the prior art²⁶ for all independent claims in their applications, and (iii) to bear the burden of specifically identifying written description support for all elements of all of their claims, whenever the total number of claims exceeds 5 independent and 25 total claims.²⁷ Each of these requirements was intentionally adopted by the PTO to shift the burdens of examination

²² See Alderucci Decl. ¶¶ 12-17, 28, 30.

²³ See 35 U.S.C. § 121; 37 CFR §1.141(a) (2006); Alderucci Decl. ¶ 13, 16-19.

²⁴ See Alderucci Decl. ¶ 27-28.

²⁵ See 72 Fed. Reg. at 46,800 (standard for the preexamination search is that used by examiners).

²⁶ The Final Rules purport to disavow this result, but the language of the Final Rules confirms it. See 72 Fed. Reg. at 46,815 (incoherently stating that the ESD requirement "is not an abdication of the examination function, or a shifting of the burden to applicant to make a *prima facie* case of entitlement to a patent," even though new Rule 1.265(a)(4) expressly requires the applicant to provide "a detailed explanation *particularly pointing out how* each of the independent claims is *patentable* over the cited references") (emphasis added); *id.* at 46,805 (denying that the Final Rules require "applicants to prove that their claims are patentable"). *Cf. id.* at 46,799 (responding to comments that the ESD requirements transfer to applicant the costs *and* responsibilities of the examination process by focusing only on the costs); *id.* at 46,798 (purporting to distinguish the required analyses from a "validity search and opinion," but nevertheless requiring a "patent novelty search, analysis, and opinion.... reduced to writing in a particular format"). At most, the PTO can state that the under the ESD requirements an applicant need not anticipate and conclusively rebut *every possible* prima-facie case. See, e.g., *id.* at 46,799, 46,803 (noting elimination of proposed § 1.265(a)(5), requiring statements of utility).

²⁷ Given the ability to file two continuation applications as of right, applicants may ultimately file up to 15 independent claims and 75 total claims without filing an ESD, so long as no single application contains more than 5 independent and 25 total claims. See 72 Fed. Reg. at 46,721.

regarding patentability from the PTO to applicants, as part of the PTO's efforts to reduce the growing number of unexamined applications.²⁸ And if applicants would not perform the PTO's work, their applications would go abandoned.²⁹

These new Rules would result in dramatic changes to examination practice and would impose dramatic new burdens on applicants.³⁰ Previously, applicants were required only to submit to the PTO information of which they were aware and reasonably believed was material to patentability, *i.e.*, information that supported a prima-facie case of unpatentability.³¹ Applicants were not required to perform searches.³² Applicants were not required to explain the potential relevance of the material information, *i.e.*, to write the examiners' office actions.³³ Applicants could not be required to identify written description support, unless examiners had established a prima-facie case that identified the specific claim element for which such support

²⁸ See, *e.g.*, 72 Fed. Reg. at 46,721, 46,791, 46,803. See also *id.* at 46,790 (rejecting alternative of changes to examiner incentives, as insufficient to address the "growing backlog of unexamined patent applications while maintaining a sufficient level of quality"); *id.* at 46,805 (refusing to answer whether the PTO would reduce examiner review time given the ESDs).

²⁹ See, *e.g.*, 72 Fed. Reg. at 46,795 (under new Rule 1.75(b)(1), if an ESD is not filed before the first action on the merits, the application "may not contain or be amended to contain more than" the claim limits); *id.* at 46,797 (new Rule 1.78(b)(3) provides a two-month, non-extendable period following notification to correct situations where ESDs were "inadvertently omitted"); *id.* at 46,725 (applicants must comply with ESD requirements following notification "to avoid abandonment" of their applications).

³⁰ See Alderucci Decl. ¶ 27. The PTO also may improperly impose additional burdens on applicants in the future, using guidance documents as if they were requirements of new Rule 1.265. See, *e.g.*, 72 Fed. Reg. at 46,804 (discussing that PTO guidance documents may be relied upon in evaluating compliance with new Rule 1.265); *McLouth Steel Corp. v. Thomas*, 838 F.2d 1317, 1320-21 (D.C. Cir. 1988) (administrative guidance documents cannot constrain agency discretion, or if they do they become substantive rules requiring notice and comment rulemaking) (citing *Community Nutrition Inst. v. Young*, 818 F.2d 943, 947-48 (D.C. Cir. 1987)).

³¹ See 37 CFR § 1.56(a)&(b) (2006) (duty to disclose information known to be not cumulative and that "establishes ... a *prima facie* case of unpatentability of a claim" or "refutes a position" the applicant has taken opposing a PTO argument of unpatentability or asserting patentability). See generally 6-19 *Chisum on Patents* § 19.03 (Fraudulent Procurement-Inequitable Conduct).

³² See, *e.g.*, *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984); ("no duty to conduct a prior art search" or otherwise disclose unknown information); 72 Fed. Reg. at 46,806 (acknowledging that there was no prior duty to search).

³³ The Final Rules do not adequately respond to comments that the ESD would require admissions and advocacy against clients' interests. See, *e.g.*, 72 Fed. Reg. at 46,802.

was purportedly lacking.³⁴ (The PTO also is seeking to impose burdens of explanation regarding a prima-facie case through new final rules regarding Information Disclosure Statements.³⁵) As a result of these changes, Cantor will lose or forego patent rights and encounter significant delays and additional costs in prosecution, adversely affecting its investments and finances.³⁶

3. Limits on Continuation Applications and RCEs

New Rules 1.78(d)(1)(i)-(v) and 1.114(f) limit the number of continuations and RCEs to two and one, respectively. New Rules 1.78(d)(1)(vi) and 1.114(g) limit the grounds for a petition to exceed these new limits to “a showing that the [new claim or] amendment, argument, or evidence sought to entered could not have been submitted [earlier].” At no point do the Final Rules clearly state any grounds on which petitions to exceed the limits on continuation applications would be granted, although the Final Rules repeatedly acknowledge that such grounds exist.³⁷ Rather, the Final Rules clearly prohibit granting petitions for *any* action that could have been taken in an earlier application.³⁸ The Final Rules also suggest that such delays violate registered practitioners’ duties under Rule 10.18(b)(2)(i),³⁹ even though that section is limited to filing papers in bad faith with an intent to delay prosecution or increase costs, and does

³⁴ See, e.g., *Hyatt v. Dudas*, 492 F.3d 1365, 1369-71 (Fed. Cir. 2007); *Alton*, 76 F.3d at 117. Cf. 72 Fed. Reg. at 46,806 (acknowledging the examiner’s responsibility to determine the lack of written description support and stating that the new rule would make it easier for examiners to do so). The Final Rules adopt new Rule 1.105(a)(1)(ix), which also eliminates the requirement for examiners to make a prima-facie case before requesting such written description identification.

³⁵ See 71 Fed. Reg. 38,821 (July 10, 2006) (proposing new Rules 1.98(a)(3)(iv)). Cantor submitted comments opposing the PTO’s proposed IDS rules.

³⁶ See Alderucci Decl. ¶¶ 18-27, 30.

³⁷ See, e.g., *id.* at 46,754; *id.* at 46,755; *id.* at 46,762; *id.* at 46,670; *id.* at 46,774. Cf. *id.* at 46,775-76, 46,777 (discussing test data grounds, for which a petition is likely to be successful).

³⁸ See, e.g., 72 Fed. Reg. at 46,756. However, the PTO has also noted that 37 CFR § 1.183 authorizes petitions to be granted notwithstanding this new categorical standard, “‘in an extraordinary situation’” where “‘justice requires.’” 72 Fed. Reg. at 46,769.

³⁹ See, e.g., *id.* at 46,768.

not relate in any way to whether a newly filed paper could have been filed earlier.⁴⁰

The PTO has effectively admitted that the new limits on continuation applications and RCEs, and the grounds for granting petitions to exceed them, establish new substantive criteria that are not required by the Patent Act.⁴¹ The PTO selected the petition standard not on the merits of the need for applicant relief or by balancing applicant and PTO interests, but because that standard is more readily determined than alternatives presented in the comments.⁴² The Final Rules also admit that the new limits on continuation applications and RCEs and the petition standard are not interpretations of the judicially developed doctrine of prosecution laches.⁴³ As a result of these changes, Cantor will lose or forego patent rights and encounter significant delays and additional costs in prosecution, adversely affecting its investments and finances.⁴⁴

⁴⁰ The PTO's position is illogical, as 37 CFR §10.18(b)(2)(i) (2006) prohibits the earlier filing of papers solely for delay, so the new filing would build off of earlier valid amendments, arguments, and evidence. That section also is a disciplinary rule, not a rule of examination procedure.

⁴¹ See, e.g., 72 Fed. Reg. at 46,767-68 (the PTO "considers the standard ... to be an appropriate balance of the interests of applicants and the need for a better focused and effective examination process to reduce the large and growing backlog of unexamined applications"); *id.* at 46,757 (the new rules including the petition and showing are a "reasonable balance" between "appropriate uses of continued examination filings" and avoiding "unnecessary prolongation of proceedings"). The new Rules cannot be required by the statute, as the PTO also stated that it "may grant relief [from the petition showing] pursuant to § 1.183." 72 Fed. Reg. at 46,777. 37 CFR §1.183 (2006) recites that the PTO cannot waive rules if "a requirement of the statute."

⁴² See *id.* at 46,768-69.

⁴³ See 72 Fed. Reg. at 46,813 (relying for the new limits and petition standard on an asserted "inherent authority to set reasonable deadlines," purportedly recognized in *In re Bogese*, 303 F.3d 1362, 1368 n.6 (Fed. Cir. 2002)); *id.* (acknowledging that the Final Rules did not seek to codify the holding in *Bogese* or the doctrine of prosecution laches). See also 71 Fed. Reg. at 50 (noting that the proposed rules did not seek to codify *Bogese* and noting the discretion in "show[ing] to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted" earlier) (emphasis added).

⁴⁴ See Alderucci Decl. ¶¶ 23-27, 29-30. Cantor will also waste money and increase PTO examination burdens by filing claims that otherwise might not have been needed. See *id.* ¶ 27.

II. ARGUMENT

A. The Final Rules Illegally Impose Substantive, Not Procedural, Requirements

Substantive, or legislative, rules are distinguished under the Administrative Procedure Act (“APA”) from interpretive rules, procedural rules, and general statements of policy. *See* 5 U.S.C. § 553(b).⁴⁵ “[A] rule is substantive when it effects a change in existing law or policy which affects individual rights and obligations.”⁴⁶ A substantive rule “encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior.”⁴⁷

In contrast, interpretive rules “merely clarify or explain existing law or regulations.”⁴⁸ Procedural rules merely “ensure ‘that agencies retain latitude in organizing their internal operations’” and “do not themselves alter the rights or interest of parties, although [they] may alter the manner in which parties present themselves or their viewpoints to the agency.”⁴⁹ General statements of policy, unlike substantive rules, do “not establish a ‘binding norm,’ ... [and are] not ... determinative of the issues or rights to which [they] are addressed.”⁵⁰ An

⁴⁵ The PTO is subject to the APA’s requirements. *See, e.g., Dickinson v. Zurko*, 527 U.S. 150, 154 (1999); *Mazzari v. Rogan*, 323 F.3d 1000, 1004 (Fed. Cir. 2003).

⁴⁶ *Lefevre v. Secretary, Dept. of Vet. Aff.*, 66 F.3d 1191, 1197 (Fed. Cir. 1995) (quoting *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991)); *See American Hospital Ass’n. v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987) (Section 553(b)’s exceptions apply only “where substantive rights are not at stake,” *i.e.*, they “are not determinative of issues or rights addressed.”); *Jerri’s Ceramic Arts, Inc. v. Consumer Product Safety Commission*, 874 F.2d 205, 207 (4th Cir. 1989) (a substantive rule “creates new law or imposes new rights or duties.”).

⁴⁷ *American Hospital Ass’n.*, 834 F.2d at 1047.

⁴⁸ *American Hospital Ass’n.*, 834 F.2d at 1045). *See Paralyzed Vets. of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998) (interpretive rules “do not intend to create new rights or duties, but only remind[] affected parties of existing duties”); *Pacific Gas & Electric Co. v. Federal Power Commn.*, 506 F.2d 33, 37 n.14 (D.C. Cir. 1974) (an interpretive rule merely “expresses the agency’s view of what another rule, regulation or statute means”).

⁴⁹ *American Hospital Ass’n.*, 834 F.2d at 1047 (quoting *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980)). *See, e.g., RSM Inc. v. Buckles*, 254 F.3d 61, 68 (4th Cir. 2001) (internal agency delegation of authority did not affect substantive rights and thus was a rule of agency organization, procedure, or practice).

⁵⁰ *American Hospital Ass’n.*, 834 F.2d at 1046. *See Pacific Gas & Electric Co.*, 506 F.2d at 38 (unlike general statements of policy, substantive rules “establish[] a standard of conduct which has the force of law”; in “administrative proceedings involving a substantive rule, the issues are *whether the adjudicated facts conform to the rule and whether the rule should be waived or*

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“agency without legislative rulemaking authority may issue only non-binding statements.”⁵¹

As clearly held by prior Federal Circuit precedents, the PTO lacks the authority to promulgate substantive rules.⁵² Grants of procedural rulemaking authority, such as that provided by 35 U.S.C. § 2(b)(2)(A), provide only “housekeeping” authority for agencies to direct their internal operations. They do not provide authority to agencies to “‘encode[] a substantive value judgment’ or to ‘substantially alter the rights or interests of regulated’ parties.”⁵³ Nor does such procedural authority provide the PTO with the power to issue rules constituting a “substantive declaration” of the Patent Act; if PTO rules are not interpretative rules, they cannot possibly “have the force and effect of law.”⁵⁴ Thus, the PTO’s rulemaking power under 35 U.S.C. § 2(b)(2)(A) simply does not supply the authority to adopt the substantive rules at issue here.

1. The Presumption of Patentable Indistinctness is Substantive

There is no doubt that the presumption of patentable distinctness is an illegal substantive rule,⁵⁵ notwithstanding the PTO’s assertions to the contrary and evasions regarding the

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applied in that particular instance.”) (emphasis added).

⁵¹ *American Hospital Ass’n.*, 834 F.2d at 1045; *Batterton*, 648 F.2d at 701 (“‘legislative’ or ‘substantive’ rules can be issued only if Congress has delegated to the agency the power to promulgate binding regulations in the relevant area”).

⁵² *See, e.g., Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-1550 (Fed. Cir. 1996) (“the broadest of the PTO’s rulemaking powers ... authorizes the Commissioner to promulgate regulations directed only to ‘the conduct of proceedings in the [PTO]’; it does NOT grant the Commissioner the authority to issue substantive rules”) (quoting 35 U.S.C. § 6(a), currently codified at 35 U.S.C. § 2(b)(2), and citing, inter alia, *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991), and *Hoechst Aktiengesellschaft v. Quigg*, 917 F.2d 522, 526 (Fed. Cir. 1990)).

⁵³ *Air Transport Assn. of Am. v. Dept. of Transportation*, 900 F.2d 369, 376, 378 (D.C. Cir. 1990) (quoting *American Hospital Ass’n.*, 834 F.2d at 1041, 1047), *vacated as moot*, 933 F.2d 1043 (D.C. Cir. 1991); *Batterton*, 648 F.2d at 702 (non-binding agency actions regulating practice... or procedure express “internal house-keeping measures organizing agency activities” but “do not foreclose alternative courses of action or conclusively [e]ffect rights of private parties”).

⁵⁴ *Animal Legal Defense Fund*, 932 F.2d at 930-31. *Cf. American Hospital Ass’n.*, 834 F.2d at 1044-45 (interpretive and procedural rulemaking exceptions to the APA are to be construed narrowly)

⁵⁵ The presumption of patentable indistinctness of new Rule 1.78(f)(2)(ii) is not a general

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presumption's consequences.⁵⁶ As the Supreme Court held in *Director, Office of Workers Compensation Programs v. Greenwich Collieries*, 512 U.S. 267 at 271, "the assignment of the burden of proof is a rule of substantive law."⁵⁷ Similarly, as the Federal Circuit held in *Paralyzed Vets. of Am. v. Secretary of Veterans Affairs*, creating (or refusing to create) factual presumptions on which agency adjudication decisions depend is substantive rulemaking.⁵⁸

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statement of policy. It is codified in the CFR and purports to have the force of law. *See, e.g., Pacific Gas & Electric Co.*, 506 F.2d at 42 (substantive rule was "'avowedly' adopted in the exercise of rulemaking power"); *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) ("an agency seems likely to have intended a rule to be legislative if it has the rule published in the Code of Federal Regulations").

⁵⁶ *See, e.g.,* 72 Fed. Reg. at 46,830 ("these rule changes involve interpretive rules, or rules of agency organization, practice, and procedure") (citing *Bachow Communs., Inc. v. Federal Communications Comm'n.*, 237 F.3d 683, 690 (D.C. Cir. 2001)). *Cf. id.* at 46,808 (the "patentably indistinct claims provisions do not affect applicant's patent rights because *once [i.e., only if] the required explanation of patentable [distinctness has been provided [by the applicant],* the claimed invention is examined on the merits and patentability is determined by the Office") (emphasis added); Although *Bachow* does state that rules at issue, governing the timing of filing of applications and permitting or suspending of amendments, were rules of agency organization, procedure, or practice under 5 U.S.C. § 553(b)(A), *Bachow* was premised on the lack of any right to file for telecommunications licenses for particular frequencies, which had previously been held to be within the Commission's substantive lawmaking power to suspend without notice and comment. *See* 237 F.3d at 690 (citing, *inter alia*, *J.E.M. Broad Co. v. Federal Communications Comm'n.*, 22 F.3d 320, 326-28 (D.C. Cir. 1994)). *See also Inova Alexandria Hospital v. Shalala*, 244 F.3d 342, 347, 349-50 (4th Cir. 2001) (finding rule to be procedural that authorized dismissals of appeal when filing dates are missed). In contrast, by statute patent applicants are entitled to have their applications examined and amendments and arguments reexamined under 35 U.S.C. §§ 131, 132(a), with the PTO required to meet its burden of proof. *See supra* at 4 & n.15. In any event, nothing in *Bachow* or in any of the cases it cites have any relevance to changes to the substantive grounds on which applications are to be evaluated for validity, such as the presumption of patentable indistinctness adopted by Rule 1.78(f)(2)(ii).

⁵⁷ 512 U.S. 267, 271 (1994) (citing *American Dredging Co. v. Miller*, 510 U.S. 443, 454 (1994)).

⁵⁸ *See Paralyzed Vets. of Am. v. Secretary of Veterans Affairs*, 308 F.3d 1262, 1266 (Fed. Cir. 2002) (noting that the new presumption of service-related causation of disease at issue in *LeFevre* was a reviewable substantive rule, and not a general statement of policy, because it "prescribed the basis on which the Department would adjudicate every claim" and reflected "a process that was 'legislative in nature'" (quoting *LeFevre*, 66 F.3d at 1197); *American Hospital Ass'n.*, 834 F.2d at 1051 (if the agency had "inserted a presumption of invalidity when reviewing certain operations, its measures would surely [be substantive and thus] require notice and comment"). *Cf. Animal Legal Defense Fund*, 932 F.2d at 928-30 (finding change in policy regarding patentability *not* to be a substantive rule only because it was a valid interpretation of intervening judicial and adjudicatory decisions and did not purport to bind examiners to follow the notice); *Pacific Gas & Electric Co.*, 506 F.2d at 43-44 (interpreting agency Order to not shift

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By adopting the presumption, the PTO has admittedly changed the rules for determining patentable indistinctness and has prejudged double patenting.⁵⁹ The presumption thus cannot be justified as an interpretation of the Patent Act, judicial doctrines, or existing PTO rules. Rather, the PTO has “substantially alter[ed] the rights or interests of [patent applicants]”⁶⁰ not only to obtain patents on distinct claims but also in avoiding terminal disclaimers that limit duration.

The new presumption of patentable indistinctness thus has impermissibly shifted the burdens of evaluating the existence of double patenting in conflict with the allocation imposed by the Patent Act.⁶¹ Further, it encodes new substantive value judgments regarding the purported need to assist efficient PTO adjudication. The reasoning of the D.C. Circuit in *Air Transport Ass’n. of Am.* is instructive. In *Air Transport Ass’n. of Am.*, the choice of what process to provide for administrative adjudication encoded a substantive value judgment “on the appropriate balance between a defendant’s *rights* to adjudicatory procedures and the agency’s *interest* in efficient prosecution.”⁶² The Final Rules similarly impose a new substantive balance.

The only question is whether the grant of *procedural* rulemaking authority to the PTO in

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the burden of proof – by precluding adjudication under particular statutory section – and thus to create only a general statement of policy; distinguishing earlier case where burden of overcoming a new general rule “was evidence of the substantive nature of the order”) (citing *Texaco, Inc. v. Federal Power Commn.*, 412 F.2d 740, 745-46 (3d Cir. 1969)).

⁵⁹ See 72 Fed. Reg. at 46,785 (“Section 1.78(f)(2) ... explicitly sets forth for the first time a presumption of patentably indistinct claims”). See also *American Mining Congress*, 995 F.2d at 1110 (distinguishing between interpretively construing a statutory provision and legislatively supplementing it or exercising judgment to effectuate it); *Batterton*, 648 F.2d at 708 & n.74 (noting non-substantive nature of the regulation upheld as procedural in *Guardian Federal Savings and Loan Association*, 589 F.2d at 665). Under the new rule, applicants whose patents previously would have been granted now will be denied based on application of the presumption (even with rebuttal) to the same evidence. Even with new evidence, the PTO will weigh the factual questions differently in light of the presumption. See *Pacific Gas & Electric Co.*, 506 F.2d at 38 (rule is substantive where it applies in adjudication, even to facts seeking to prove that the rule should be waived).

⁶⁰ *Air Transport Assn. of Am.*, 900 F.2d at 378.

⁶¹ See *supra* at 3-4 & n.15.

⁶² 900 F.2d at 379 (first emphasis in original).

35 U.S.C. § 2(b)(2)(A) permits the PTO to establish the new *substantive* presumption of patentable indistinctness contrary to the statute. The question answers itself – No. The PTO’s housekeeping authority simply cannot be extended to justify new rules encoding substantive policy judgments (particularly that revise statutory defaults) and imposing new obligations on applicants.⁶³ This is precisely the kind of substantive rulemaking authority that the PTO lacks.

The dicta of *Stevens v. Tamaï*⁶⁴ regarding the PTO’s authority to establish burdens of proof is readily distinguished, particularly as the rule at issue was authorized as an interpretation of a substantive statutory provision.⁶⁵ In *Stevens*, the rules at issue provided that the party in an interference seeking to establish relief requested by a motion bears the burden of proof, and that when a party seeks to establish invention priority by relying on a foreign-language application it must file a translation and an affidavit certifying to its accuracy.⁶⁶ The movant failed to do so, but argued it should have been entitled to priority anyway because its application was examined without a verified translation (as was authorized by other statutory provisions, with which the rules were supposedly in conflict).⁶⁷ The Federal Circuit rejected this argument, given the separate statutory authority for the PTO to require a verified translation.⁶⁸ It was in this context that the Federal Circuit stated that the rules were a permissible exercise of the PTO’s authority to “allocate the burdens associated with [expeditiously resolving interferences] in a reasonable

⁶³ Similarly, 35 U.S.C. § 2(b)(2)(C) cannot justify the new Rule, as that section addresses only rules to “facilitate and expedite the processing of patent applications, particularly [electronic applications]... subject to ... the confidential status of applications.”

⁶⁴ 366 F.3d 1325 (Fed. Cir. 2004).

⁶⁵ See 35 U.S.C. § 372(b)(3). Cf. *PTO PI Brief* at 21, 23 (relying on *Stevens*, 366 F.3d at 1333, as providing authority for the Final Rules).

⁶⁶ See *Stevens*, 366 F.3d at 1328 (citing 37 CFR §§ 1.633(f), 1.637(a)&(f), and 1.647 (2003)).

⁶⁷ See *id.* at 1331-32 (citing 35 U.S.C. §§ 363 and 371(c)(2)).

⁶⁸ *Id.* at 1333 (noting that 35 U.S.C. § 372(b)(3) permits the Director to “require a verification of the translation.”).

manner *not inconsistent* with the statutory scheme.”⁶⁹ But imposing verification obligations pursuant to a substantive grant of regulatory authority is not an exercise of procedural rulemaking power to establish burdens of proof. Further, requiring a certified translation is wholly dissimilar to imposing substantive value judgments of double patenting for all relevant applications through a presumption of patentable indistinctness. And unlike in *Stevens*, the Patent Act itself allocates to the PTO the burden of proving patentable distinctness,⁷⁰ and thus new Rule 1.78(f)(2)(ii) conflicts with the statute rather than being authorized by it.

The dicta in *In re Van Ornem*⁷¹ also are distinguishable, as *Van Ornem* actually addressed a rule interpreting and codifying existing case law. The PTO had met its burden to make a valid obviousness-type double patenting rejection, but determined under the applicable terminal disclaimer rule that the requisite disclaimer to assure common ownership could not be supplied (because the earlier patent had been assigned to another party by the applicant’s owner).⁷² The Court upheld the rejection and the PTO’s terminal disclaimer regulation requiring common ownership.⁷³ In doing so, the Court noted that the relevant regulatory language was “precisely” the language of a terminal disclaimer that had been approved in an earlier case.⁷⁴ The Court also noted that the rule had been adopted immediately after that case, and recited the long history of case law underlying the requirement for common ownership.⁷⁵ As with *Stevens*, having found that the rule was authorized under existing substantive law, the Court rejected the argument that the PTO’s housekeeping rulemaking authority did not authorize the rule.⁷⁶ In contrast, new Rule

⁶⁹ *Id.* at 1333 (emphasis added).

⁷⁰ *See supra* at 4 & n.15.

⁷¹ 686 F.2d 937 (C.C. P.A. 1982). *Cf. PTO PI Brief* at 22-23 (relying on *Van Ornem*).

⁷² *See id.* at 945.

⁷³ *See id.* at 942-46.

⁷⁴ *In re Griswold*, 365 F.2d 834, 840 n.5 (C.C.P.A. 1966).

⁷⁵ *See id.* at 945; *supra* at 3 & n.11.

⁷⁶ *See id.* at 946-48 (citing, *inter alia*, *In re Zickendraht*, 319 F.2d 225 (C.C.P.A. 1963), and *In re*

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1.78(f)(2)(ii) expressly alters requirements for the PTO to establish double patenting rejections in the first instance, and in doing so conflicts not only with the existing statutory requirements but also with established case law placing those burdens on the PTO.⁷⁷

2. The Requirements to Prove Patentability Are Substantive

There is no doubt that the claim limits in new rule 1.75(b)(1), triggering the requirements to search for prior art, to prove patentability, and to explain written description support of new Rule 1.265(a)(1), (4) and (5), are illegal substantive rules. New Rule 1.75(b)(1) encodes the substantive value judgment that more than the specified number of claims imposes purportedly excessive burdens supposedly authorizing the PTO to shift to applicants its examination obligations.⁷⁸ Nothing like this requirement previously existed in the PTO's rules or the case law, including 37 CFR § 1.105,⁷⁹ and thus new Rule 1.75(b)(1) is not an interpretive rule. Nor is new Rule 1.75(b)(1) a housekeeping measure, as it triggers requirements that dramatically affect applicants' substantive rights, imposing duties enforced by the threat of abandonment.⁸⁰

Similarly, new Rules 1.265(a)(1),(4)&(5) clearly change existing law and policy, and are

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Braithwaite, 379 F.2d 594 (C.C.P.A. 1967)), and noting that *Braithwaite*'s holding clearly "contemplate[d] common ownership"). In contrast, the dissent in *Van Ornem* believed that the rule was contrary to 35 U.S.C. § 261 and not supported by the judicially developed case law, and thus that it exceeded the PTO's procedural rulemaking authority. *See id.* at 949-51.

⁷⁷ It should go without saying that the PTO's reliance on *Bogese*, *PTO PI Brief* at 21, also misplaced. *Bogese* addressed a PTO *adjudicatory* decision to refuse to process claims that, following notice, were not being diligently prosecuted. The Court suggested that the PTO's authority to sanction undue delay was at least as extensive as existing case law governing unenforceability of patents for prosecution delays. *See* 303 F.3d at 1367-68.

⁷⁸ *See American Hospital Ass'n.*, 834 F.2d at 1047; *supra* at 4 n.15.

⁷⁹ *Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2005), provides no authority for compelling applicants to do the PTO's prior art searching or to develop arguments to rebut a prima-facie case that has not been made by the examiner. *See* 72 Fed. Reg. at 1279-80, 1283-85 (failure to respond to a non-arbitrary request under 37 CFR § 1.105 for information in the applicant's possession regarding sales conduct, which might have demonstrated a statutory bar under 35 U.S.C. § 102(b), provided the PTO with authority to treat an application as abandoned).

⁸⁰ *See, e.g., Lefevre*, 66 F.3d at 1197; *American Hospital Ass'n.*, 834 F.2d at 1047..

neither interpretive nor procedural rules.⁸¹ These new Rules shift the burdens of proving unpatentability from the PTO to the applicant, which is a substantive not a procedural change.⁸² Further, these new Rules do not merely alter the manner in which applicants present their applications and arguments to the PTO,⁸³ but rather dramatically change the nature of the applicants' arguments and of the examination process.

3. The Limits on Continuation Applications Are Substantive

There is no doubt that the limits on continuation applications and RCEs of new Rules 1.78(d)(1)(i)-(v) and 1.114(f) are illegal substantive rules. These new Rules encode the substantive value judgment that more than two continuation applications and one RCE impose purportedly excessive burdens that supposedly authorize the PTO to prohibit additional applications and RCEs, to achieve an "appropriate" policy balance to address the growing examination backlog.⁸⁴ Nothing like these requirements previously existed in the PTO's rules or the case law, particularly as they are contrary to 35 U.S.C. § 120 and case law interpreting it.⁸⁵ Thus, the new Rules are not interpretations of the existing statute, the law of practitioner discipline, or the judicially developed law of prosecution laches.⁸⁶ Nor are the new Rules mere housekeeping measures or otherwise permissible procedural requirements to compel disclosure of information already in the applicant's possession.⁸⁷ Rather, these rules cut off applicants'

⁸¹ See *Lefevre*, 66 F.3d at 1197.

⁸² See *Director, Office of Workers Compensation Programs v. Greenwich Collieries*, 512 U.S. 267 at 271; *supra* at 12-13.

⁸³ Cf. *American Hospital Ass'n.*, 834 F.2d at 1047.

⁸⁴ 72 Fed. Reg. at 46,767. See *American Hospital Ass'n.*, 834 F.2d at 1047.

⁸⁵ See, e.g., *In re Henrickson*, 399 F.2d 253, 256-62 (C.C.P.A. 1968); *In re Hogan*, 559 F.2d 595, 603-05 (C.C.P.A. 1977). Cf. *Alabama Power Co. v. Costle*, 636 F.2d 323, 359-61 (D.C. Cir. 1979) (administrative convenience and the difficulty of regulation does not permit an agency to create exceptions contrary to statute). Cantor adopts the Plaintiffs' arguments that the new limits are contrary to 35 U.S.C. § 120, and cannot be justified as interpretations of the statute.

⁸⁶ See *supra* at 8-9 & nn. 39-43.

⁸⁷ See 37 CFR § 1.105 (2006); *supra* at 17 & n.79.

substantive rights⁸⁸ to seek additional claims through continuation applications and RCEs filed in good faith.

The fact that the PTO has provided for petitions to exceed the limits if applicants meet the requisite substantive standard does not make the new Rule 1.78(d) limits any less substantive. First, the PTO already had the authority to waive its rules based on a petition under Rule 1.183 or to amend its rules (as required by the APA).⁸⁹ The rules thus adopt only the new substantive limits. Second, new Rules 1.78(d)(vi) and 1.114(g) themselves are substantive rules, as they adopt substantive restrictions on granting petitions (encoding substantive value judgments).⁹⁰ The fact that the PTO has not clarified how it would exercise its discretion when the substantive restrictions are met, or has reserved some discretion to disregard those restrictions, does not make the new Rules any less substantive.⁹¹

B. The Final Rules Illegally Shift Burdens of Proof.

As noted above, the Patent Act imposes on the PTO the burden of persuasion in regard to determining that claims are unpatentable.⁹² Shifting to applicants the PTO's burdens of persuasion to prove patentable indistinctness under new Rule 1.78(f)(2)(ii) and to prove additional grounds of unpatentability under new Rules 1.75(b)(1) and 1.265(a)(1), (4) and (5) thus is contrary to the Patent Act. These new Rules are therefore invalid. Further, unless it were otherwise specifically authorized by the Patent Act (as in *Stevens*), the PTO may not by rule remove these burdens of persuasion from examiners, as to do so would violate the APA. The

⁸⁸ Cf. *Lefevre*, 66 F.3d at 1197; *Jerri's Ceramic Arts*, 874 F.2d at 207.

⁸⁹ See 37 CFR § 1.183 (2006); 5 U.S.C. § 553(e).

⁹⁰ See *Lefevre*, 66 F.3d at 1197; *American Hospital Ass'n.*, 834 F.2d at 1047.

⁹¹ See, e.g., *McLouth Steel Corp.*, 838 F.2d at 1321 (noting that language regarding retained discretion to deviate from a policy did not prevent the agency's reliance on that policy from being a substantive rule).

⁹² See *supra* at 4 & n.5.

APA provides that, “[e]xcept where otherwise provided by statute, the proponent of a rule or order has the burden of proof.”⁹³ Because examiners must issue adjudicatory orders in order to reject applications, they are the proponents of such orders. Accordingly, the APA prevents the PTO from shifting the burden of persuasion, and to do so would interfere with the APA’s goal of assuring uniformity of approach among federal agencies in this regard.⁹⁴

Even if new Rules 1.78(f)(2)(ii), 1.75(b)(1), and 1.265(a)(1), (4) and (5) only shifted from the PTO to applicants the burden of producing a prima-facie case of unpatentability, they would be invalid. Agencies may resolve issues for adjudication (even if only tentatively) through rulemaking, but only for the types of issues that do not require case-by-case adjudication.⁹⁵ Thus, the issues must not be unique to the applicant, and must “be resolved as fairly through rulemaking” as through adjudication considering the evidence.⁹⁶ That is not the case for determining the patentability of patent claims, given that the claims and their relationships to other applications, patents, and prior art vary for each and every patent application. The Final Rules also lack any legislative facts in the record to support factual

⁹³ 5 U.S.C. § 556(d). Although this section applies by its terms only to rulemaking proceedings under Section 553 and to formal hearings under Section 554, the relevant principle should not change given the initial allocation of the burden of persuasion to the PTO by the Patent Act.

⁹⁴ See *Director, Office of Workers Compensation Programs v. Greenwich Collieries*, 512 U.S. at 280-81.

⁹⁵ See *Heckler v. Campbell*, 461 U.S. 458, 46 (1983).

⁹⁶ *Id.* at 468 (citing *Am. Airlines, Inc. v. CAB*, 359 F.2d 624, 633 (D.C. Cir. 1966) (en banc)).

inferences of unpatentability that might rationally justify shifting the burdens of production from the PTO to applicants.⁹⁷ In sum, these rules cannot stand as they have no foundation.

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Respectfully submitted,

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⁹⁷ See 5 U.S.C. § 706(2)(A)&(E); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (requiring a rational connection between the facts found and the choices made); *In re Lee*, 277 F.3d 1338, 1342 (Fed. Cir. 2002) (judicial review is premised on an agency's ability to make required findings and to show the evidence on which they are based); *supra* at 4 & n.18 (discussing the lack of evidence in the record). In regard to Rule 1.78(f)(2)(ii), the Final Rules note that the presumption of patentable indistinctness applies "only to applications that *most likely* contain patentably indistinct claims." 72 Fed. Reg. at 46,784 (emphasis added). But the Final Rules provide no evidence for either meaning of the emphasized words –that applications subject to the new rule are the most likely kinds of applications to contain indistinct claims or that such applications are highly likely to do so.

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of December 2007, I electronically filed in Case Nos. 1:07cv1008 and 1:07cv846 (JCC/TRJ) the foregoing "**BRIEF OF AMICUS CURIAE CANTOR FITZGERALD PATENT HOLDINGS IN SUPPORT OF PLAINTIFFS' SUMMARY JUDGMENT MOTION**" and "**DECLARATION OF DEAN ADLERUCCI IN SUPPORT OF BRIEF OF AMICUS CURIAE CFPH, LLC**" using the CM/ECF system and that service was thereby accomplished on:

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