

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

TRIANTAFYLLOS TAFAS,	:	
	:	
	:	
Plaintiff,	:	
	:	
v.	:	1:07cv846 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

CONSOLIDATED WITH

SMITHKLINE BEECHAM	:	
CORPORATION,	:	
d/b/a GLAXOSMITHKLINE, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	1:07cv1008 (JCC/TRJ)
	:	
JON W. DUDAS, et al.,	:	
	:	
Defendants.	:	

**GLAXOSMITHKLINE’S OPPOSITION TO DEFENDANTS’ MOTION FOR
SUMMARY JUDGMENT AGAINST THE “GLAXOSMITHKLINE” PLAINTIFFS**

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TABLE OF ABBREVIATIONS FOR CITATIONS TO COURT FILINGS

Abbreviation	Document
GSK SJ Br.	Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
Knowles Decl.	Declaration of Sherry M. Knowles, Exhibit 4 (Docket No. 142-11) to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
Manbeck Decl.	Declaration of Harry F. Manbeck, Jr., Exhibit 5 (Docket No. 142-12) to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
Ex. ____ (1-26)	Exhibits to the Memorandum in Support of GlaxoSmithKline's Motion for Summary Judgment, Docket No. 142 in 1:07cv846
PTO SJ Br.	Memorandum in Support of Defendants' Motion for Summary Judgment, Docket No. 141 in 1:07cv846
AIPLA SJ Br.	Brief of <i>Amicus Curiae</i> American Intellectual Property Law Association, Docket No. 185 in 1:07cv846
L. Profs. Br.	Brief of <i>Amicus Curiae</i> Intellectual Property, Administrative Law and Public Health Professors in Support of Defendants' Anticipated Motions for Summary Judgment, Docket No. 232 in 1:07cv846
Micron Br.	Brief of <i>Amicus Curiae</i> Micron Technology, Inc., in Support of Defendants' Anticipated Motion for Summary Judgment, Docket No. 229 in 1:07cv846
PPF Br.	Brief of <i>Amicus Curiae</i> Public Patent Foundation, <i>et al.</i> , in Support of Defendants' Anticipated Motions for Summary Judgment, Docket No. 228 in 1:07cv846
Am. Compl.	Verified Amended Complaint, Docket No. 5 in 1:07cv1008
PTO TRO Opp. Br.	PTO Opposition to Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, Docket No. 46 in 1:07cv1008
AIPLA TRO Br.	Brief of <i>Amicus Curiae</i> American Intellectual Property Law Association in Support of "GSK" Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction, Docket No. 30-1 in 1:07cv1008
TRO Hr'g Tr.	October 31, 2007 Hearing Transcript, Docket No. 69 in 1:07cv1008

I. INTRODUCTION.

In its October 31, 2007 Memorandum Opinion, this Court correctly enjoined implementation of the *ultra vires* Final Rules as likely contrary to law. *GlaxoSmithKline v. Dudas*, 511 F. Supp. 2d 652 (E.D. Va. 2007). In its first opportunity to address the controlling issues of this case since the injunction, the PTO offers newly contrived and inconsistent arguments that bolster GSK's positions and this Court's preliminary ruling.

In its brief, the PTO primarily argues that it has the authority to promulgate the Final Rules and, therefore, is entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). But what the PTO ignores is that where Congress withholds rulemaking authority from an agency, the Supreme Court has made clear that the agency is entitled to no deference. *Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990). Inexplicably, despite *Adams Fruit's* prominence in this case, neither the PTO in its 70-page moving brief, nor the *amici* who support the PTO acknowledges *Adams Fruit* even once.

Unable to take refuge in *Chevron* or surmount *Adams Fruit*, the PTO nevertheless forges ahead with its substantive power grab. The PTO now nakedly asserts that it possesses substantive rulemaking authority. Until now, the PTO had not claimed such authority—not when it promulgated the Final Rules; not when it opposed GSK's request for preliminary relief; and not when it argued at the preliminary injunction hearing. But, in addition to representing a *post hoc* rationalization of counsel that cannot stand because the agency did not adopt it in the rulemaking documents, the PTO's new-found argument falters under *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996), in which the Federal Circuit made clear, in the wake of *Adams Fruit*, that the PTO lacks any such substantive rulemaking authority. Undaunted, the PTO grasps at another new and indefensible position that cannot be squared with *Merck*—that the distinction between substantive and procedural rules is a “false dichotomy.”

Despite its protestations to the contrary, the PTO cannot escape the fact that the Final Rules directly conflict with governing statutes and affect substantive rights as they have been interpreted by controlling judicial decisions for decades. *See, e.g., In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (holding that there is no statutory basis for imposing an “arbitrary limit” on the number of allowable continuing applications); *In re Wakefield*, 422 F.2d 897, 900 (C.C.P.A. 1970) (“[T]here is no statutory authority for rejecting claims as being ‘unnecessary.’ [Rather], an applicant should be allowed to determine the necessary number and scope of his claims, provided he pays the required fees and otherwise complies with the statute.”). Final Rule 78 limits applicants to two continuing applications in direct contradiction to section 120’s lack of any such limit. Final Rule 114 limits applicants to one request for continued examination (“RCE”) per application family although section 132 contains no such limit. Final Rule 75 limits the number of claims an applicant may seek although section 112 contains no such limit. Because these Final Rules expressly limit applicants’ substantive rights under the Patent Act, they are substantive rules, not procedural ones.

As it has for some time now, the PTO wrongly asserts that the limits: (i) are “procedural”; (ii) are not limits at all; or (iii) that the doctrine of prosecution laches allows the PTO to impose limits. Yet there can be no doubt that these Final Rules impose substantive restrictions on applicants. In fact, the PTO has even announced that these rules will limit continuing applications, RCEs, and claims. And this comes as little surprise, given that the very purpose of these rules is to reduce the backlog looming at the PTO. Moreover, the PTO attempts to use the doctrine of prosecution laches to justify its limits, but in doing so, ignores the Federal Circuit’s most recent case on the doctrine—*Symbol IV*—upon which this Court relied in preliminarily enjoining the Final Rules, and which warns that the doctrine is to be invoked

“sparingly lest statutory provisions be unjustifiably vitiated” and “applied only in egregious cases.”

The PTO exacerbates its unlawful rulemaking by applying these rules retroactively, although, as it now concedes, Congress has granted it no such authority. While the PTO asserts that applying the Final Rules to its “backlog” will improve “administrative efficiency,” the truth is that the Final Rules will have little, if any, impact on the PTO’s backlog. Instead, the only significant impact that these Final Rules will have is to harm GSK and other innovators to the detriment of the public health and the public’s interest in promoting innovation. As GSK has described, and the PTO ignored, the Final Rules will destroy the *quid pro quo* bargain inherent in already filed GSK patent applications, thereby putting at risk hundreds of millions of dollars of capital, eviscerating business certainty, and destroying proprietary rights in patent applications. The PTO suggests that patent applicants lack any sort of property interest in their patent applications, but, in so doing, ignores the Takings Clause of the Constitution; controlling Supreme Court precedent, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984); and the Patent Act itself (which, not surprisingly, Congress designed to *protect* property rights, not run roughshod over them).

Further, the PTO essentially concedes that the preexamination search of its new examination support document (“ESD”) requirement is hopelessly vague. Not once has the PTO identified what it would consider to be an adequate search. Rather, the PTO argues that the search requirement “cannot . . . be read in isolation.” But none of the eight extraneous “guidance” documents it invokes in an attempt to cure facial vagueness actually do so. They fall woefully short, leaving applicants to guess how to comply with the ESD requirement.

For at least these reasons, and as set forth in more detail below, GSK respectfully urges the Court to enforce congressional and constitutional limits on the PTO's sphere of authority, and vacate the Final Rules.¹

II. THE PTO'S MOTION MUST BE DENIED BECAUSE GSK IS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON ALL CAUSES OF ACTION.

A. The PTO Lacks Substantive Rulemaking Authority, Cannot Promulgate Rules Inconsistent With Established Law, And Is Entitled To No Deference When It Attempts To Do So.

The PTO lacks substantive rulemaking authority. *See Merck*, 80 F.3d at 1549-50. Despite this, the PTO asserts that the Final Rules fall within its power to “‘establish regulations, not inconsistent with law’ to ‘govern the conduct of proceedings in the Office,’” to “‘facilitate and expedite the processing of patent applications,’” and to “‘govern the . . . conduct of . . . parties before the Office.’” (PTO SJ Br. 14-15 (citing 35 U.S.C. §§ 2(b)(2)(A), (C), (D), respectively).) This argument fails on several fronts.

First, the Final Rules are substantive because they affect applicants' rights and obligations. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) (Substantive rules are those that “affect[] individual rights and obligations.”); *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (stating that substantive rules are those that “effect[] a change in existing law or policy which affect[] individual rights and obligations”) (internal quotations omitted). The Final Rules limit continuing applications, RCEs, and claims. *See infra* §§ II.B., II.D.; (*see also* Ex. 18 at A00432 (“Why Limit Continuations?”), A00434 (“Why Limit

¹ GSK disputes the PTO's “Statement of Material Undisputed Facts.” (*See* PTO SJ Br. 7-13.) Many of the purported facts are merely unsupported assertions. (*See, e.g., id.* at 7 (stating without factual support that a “substantial portion of th[e] backlog is attributable” to “negligent” or “deliberate” practices that “unnecessarily prolong prosecution through use of repetitive and vexatious continuing applications”).) GSK shows herein and in its opening summary judgment brief why those assertions are incorrect, and, ultimately, why the Final Rules are unlawful. (*See, e.g., GSK SJ Br. 7-12.*)

Claims?”).) Those limits affect GSK’s substantive rights, including rights under sections 102, 103, 112, 120, 132, and 154(d), among others. For example, the limit on continuing applications denies GSK its statutory right to the filing date of a prior application, which will affect its rights under sections 102 and 103 and result in the denial of an otherwise meritorious patent. (*See* Manbeck Decl. ¶¶ 14-19.) The limit on RCEs denies GSK its statutory rights under section 132 to an unlimited number of RCEs per application “at the request of the applicant.” (*Id.* ¶¶ 27-29, 40.) The limit on claims denies GSK its statutory right under section 112 to use “one or more claims” to define its inventions. (*Id.* ¶¶ 12, 43-46.) Further, the imposition of the claims limit on pending published applications strips GSK of its provisional rights expressly provided for in section 154(d). Thus, the Final Rules are substantive.

As a result, the Final Rules are not entitled to any deference, because Congress carefully confined the PTO’s authority under section 2 to procedural matters and did not authorize the PTO to interpret the terms of the Patent Act itself. *See Adams Fruit*, 494 U.S. at 649. (“A precondition to deference under *Chevron* is a congressional delegation of administrative authority.”); *see also Williams v. Taylor*, 529 U.S. 362, 387 n.13 (2000) (*Chevron* deference “depends on delegation.”); *Pesquera Mares Australes Ltda. v. United States*, 266 F.3d 1372, 1381 n.6 (Fed. Cir. 2001) (citing *Merck* for its holding that the PTO lacks substantive rulemaking authority and, thus, cannot claim *Chevron* deference); *Small v. United States*, 158 F.3d 576, 581 n.1 (Fed. Cir. 1998) (same); *Hodge v. West*, 155 F.3d 1356, 1361 (Fed. Cir. 1998) (same). It is not enough that an agency possesses some power to issue regulations over *some aspects* of a statute. As the Supreme Court explained in *Adams Fruit*:

Congress clearly envisioned, indeed expressly mandated, a role for the Department of Labor in administering the [Agricultural Worker Protection Act (“AWPA”)] statute by requiring the Secretary to promulgate *standards* implementing AWPA’s motor vehicle provisions. This delegation, however, does

not empower the Secretary to regulate the scope of the judicial power vested by the statute. Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental “that *an agency may not bootstrap itself into an area in which it has no jurisdiction.*”

494 U.S. at 650 (first emphasis in original; all other emphasis added) (citation omitted). In such circumstances, *Chevron* deference is inapplicable. See *A.T. Massey Coal Co. v. Holland*, 472 F.3d 148, 167 (4th Cir. 2006) (according no deference to the Social Security Administration when Congress did not delegate the authority to interpret the provisions of the Coal Act); see also *Atchison, Topeka & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437, 441 (7th Cir. 1994) (en banc) (no delegation to Federal Railway Administration over hours of service) (relied upon prominently by the Federal Circuit in *Merck*), *aff’d sub nom. Bhd. of Locomotive Eng’rs v. Atchison, Topeka & Santa Fe R.R. Co.*, 516 U.S. 152 (1996). Congress did not vest the PTO with substantive rulemaking authority, and, therefore, the Final Rules are not entitled to any deference.

Furthermore, the Patent Act and the Federal Circuit’s authoritative construction of that Act control the rights attendant to continuing applications, RCEs, and claims. The PTO cannot alter longstanding practice under those provisions without an express delegation from Congress. See *Lechmere, Inc. v. NLRB*, 502 U.S. 527, 536-37 (1992) (Once courts “have determined a statute’s clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency’s later interpretation of the statute against our prior determination of the statute’s meaning.”); see also *ITT Indus., Inc. v. NLRB*, 413 F.3d 64, 68 (D.C. Cir. 2005) (stating that the *Lechmere* principle, where applicable, displaces *Chevron* deference).²

² The PTO asserts that it is entitled to deference under *National Cable & Telecommunications Ass’n v. Brand X Internet Services*, 545 U.S. 967 (2005) (“*Brand X*”), alleging that, for *Lechmere* to apply, the courts must hold that judicial interpretations that precede agency interpretations are the only possible way to interpret the statute at issue and that the *Henriksen* case “did not hold that Section 120 unambiguously disallows putting conditions on continuation filings.” (PTO SJ

Second, the PTO's attempts to enclose its Final Rules within the framework of *Chevron* are unavailing. (See PTO SJ Br. 13-20.) As part of this effort, the PTO completely ignores *Adams Fruit* in its 70-page opening brief, despite GSK's reliance on *Adams Fruit* since day one and this Court's reliance on *Adams Fruit* in preliminarily enjoining the Final Rules' implementation, see *GlaxoSmithKline*, 511 F. Supp. 2d at 663-64.³ Similarly, the *amicus* law professors who support the PTO fail to address *Adams Fruit*; instead, they assert that "the first logical question in evaluating the regulations is whether *Chevron* is applicable." (See L. Profs. Br. 3.)⁴ Under *Adams Fruit*, however, the first question is whether Congress has delegated relevant rulemaking power to the PTO. The answer to that question here is a resounding "NO."

Br. 25 (citing *Brand X*, 545 U.S. at 982).) *Brand X*, however, is inapplicable for several reasons. First, *Brand X* applies only if an agency is entitled to *Chevron* deference, and here the PTO is not. 545 U.S. at 982. Second, courts have held that the language of section 120 is unambiguous. *In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968) (holding that there is no statutory basis for imposing an "arbitrary limit" on the number of allowable continuing applications); see also *In re Hogan*, 559 F.2d 595, 604 (C.C.P.A. 1977) (stating that the language of section 120 is "clear and unambiguous"). Lastly, controlling Federal Circuit authority unambiguously directs that the doctrine of prosecution laches should only be "used sparingly lest statutory provisions be unjustifiably vitiated . . . [and] should be applied only in egregious cases of misuse of the statutory patent system." *Symbol Techs., Inc. v. Lemelson Med., Educ., & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("*Symbol IV*").

³ The PTO's failure to address *Adams Fruit* is consistent with its failure to address the case during its rulemaking process, which is a separate ground for vacating the PTO's actions as arbitrary and capricious: "[I]f [agency] action is based upon a determination of law as to which the reviewing authority of the courts does come into play, an order may not stand if the agency has misconceived the law." *Prill v. NLRB*, 755 F.2d 941, 947 (D.C. Cir. 1985) (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943)).

⁴ The PTO and the *amicus* law professors who support it also assert that the Supreme Court's decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999), worked a sea change in judicial review of the PTO by declaring that the PTO is subject to ordinary administrative law principles. (PTO SJ Br. 16 n.8; L. Profs. Br. 1.) However, *Dickinson* merely held that the arbitrary and capricious standard of review, rather than a clearly erroneous standard, applied to the PTO's fact-finding in its adjudications. 527 U.S. at 152. Critically, though, the Final Rules involve PTO rulemaking rather than adjudication. Thus, *Dickinson* is irrelevant to whether the PTO possesses the authority to issue the Final Rules.

The PTO also asserts it is entitled to *Chevron* deference because section 2(b)(2) grants it rulemaking authority. (See PTO SJ Br. 14.) But that misses the point. The issue is not whether the PTO has *some* rulemaking authority, but whether it possesses the *relevant substantive* rulemaking authority to pass *these rules*. See *Merck*, 80 F.3d at 1549-50. *Merck* unambiguously states that the PTO lacks substantive rulemaking power, contrary to the PTO's attempts to distinguish the case (see PTO SJ Br. 17-20).⁵ In fact, *Merck* is in line with *Adams Fruit*, as the *Merck* court stated that "only statutory interpretations by agencies WITH RULEMAKING POWERS deserve substantial deference." 80 F.3d at 1549 (emphasis in original) (quoting *Atchison, Topeka*, 44 F.3d at 441).⁶ Thus, the PTO's bid for *Chevron* deference should be denied.

The PTO's new claim that Congress delegated substantive rulemaking authority to it clearly goes too far. (PTO SJ Br. 20, 49 n.30.) Not to be mistaken, the PTO reiterates its ambitious new claim to power, stating specifically that "the USPTO disputes . . . the proposition that the USPTO lacks substantive rulemaking authority." (*Id.* 49 n.30.) For over a decade, it has been abundantly clear that the PTO lacks such substantive rulemaking authority. *Merck*, 80 F.3d at 1549-50; *Brand v. Miller*, 487 F.3d 862, 869 n.3 (Fed. Cir.) ("[W]e have held in any event that the Board does not earn *Chevron* deference on questions of substantive patent law."), *cert.*

⁵ The fact that Congress has recently considered but expressly declined to grant the PTO substantive rulemaking authority further evidences the fact that the PTO currently lacks such authority. (See GSK SJ Br. 18; Manbeck Decl. ¶ 9.)

⁶ In *Atchison, Topeka*, the Seventh Circuit made clear that it was applying *Adams Fruit* in rejecting an assertion of *Chevron* deference. 44 F.3d at 445 (Easterbrook & Manion, JJ., Posner C.J., concurring) ("The Federal Railway Administration has not been delegated either rulemaking or adjudicative power over the subject of hours of service. It therefore cannot demand obedience to its law-making choices after the fashion of *Chevron* . . . See *Adams Fruit* . . ."). In affirming *Atchison, Topeka*, the Supreme Court did not address the question of deference at all, because the *en banc* ruling of the Seventh Circuit was so clearly correct on that issue. See *Bhd. of Locomotive Eng'rs*, 516 U.S. 152.

denied, 128 S. Ct. 650 (2007); *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003). As the Federal Circuit recently explained, ““an agency literally has no power to act . . . unless and until Congress confers power upon it.”” *Agro Dutch Indus. Ltd. v. United States*, 508 F.3d 1024, 1033 (Fed. Cir. 2007) (quoting *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986)).

The PTO also errs by overlooking *Adams Fruit* and invoking so-called *Skidmore* deference as an alternative argument. (PTO SJ Br. 20 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).) *Skidmore* deference is irrelevant because the Supreme Court has held that ***no deference*** is due where the agency acts outside its delegated authority and instead has conferred interpretive authority on the judiciary. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 161-62 (4th Cir. 1998) (discussing *Chevron* and *Adams Fruit*), *aff’d*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000); *see also Am. Bar Ass’n v. FTC*, 430 F.3d 457, 468-70 (D.C. Cir. 2005); *Sac & Fox Nation of Mo. v. Norton*, 240 F.3d 1250, 1265-66 (10th Cir. 2001) (“Because the Secretary lacked authority to interpret the term ‘reservation,’ . . . we owe no deference to his interpretation Instead, we proceed to decide for ourselves the meaning of the term ‘reservation,’ as used in IGRA.”) (citations omitted); *New York State Bar Ass’n v. FTC*, 276 F. Supp. 2d 110, 140 (D.D.C. 2003) (“[T]he FTC’s interpretation falls beyond the pale of both *Chevron* and *Skidmore* and thus is entitled to no deference.”). Thus, the PTO’s alternative bid for *Skidmore* deference should also be rejected.

Third, the cases upon which the PTO relies do not support its substantive power grab. (See PTO SJ Br. 15-16.) Instead, the cases discuss procedural rules. *See Lacavera v. Dudas*, 441 F.3d 1380, 1382 (Fed. Cir. 2006) (concerning the PTO’s refusal to conduct the procedure of registering a foreign national to fully practice before it), *cert. denied*, 127 S. Ct. 1246 (2007);

Stevens v. Tamai, 366 F.3d 1325, 1332-33 (Fed. Cir. 2004) (relating to the PTO's procedural requirement that a party submit a translation of a foreign language application during an interference proceeding).⁷

The PTO then asserts that the Final Rules are procedural and not substantive because they do not affect GSK's rights to receive a patent if GSK's applications comply with 35 U.S.C. §§ 101, 102, 103, and 112. (PTO SJ Br. 18-19.) This is simply wrong. As explained above, the Final Rules are substantive because they affect applicants' rights and obligations. *See Animal Legal Def. Fund*, 932 F.2d at 927.

The PTO further asserts that it can issue procedural regulations, even if such regulations may have substantive effects. (PTO SJ Br. 19-20.) This directly contradicts the PTO's prior representations to this Court. (*See* TRO Hr'g Tr. at 42-43 ("These are procedural rules . . . [that] **do not affect** the substantive eligibility criteria for getting a patent. They **don't affect** the criteria of novelty. . . . That's what's substantive in getting a patent. . . . They're procedural for that reason as well.") (emphasis added).) In reaching for that authority, the PTO relies on two inapposite cases. *In re Van Ornum* stands for the proposition that the PTO can issue procedural regulations that comport with statutory and case law. 686 F.2d 937, 945 (C.C.P.A. 1982). Here,

⁷ The PTO also cites to *Morganroth v. Quigg*, 885 F.2d 843 (Fed. Cir. 1989), as supporting its position. (PTO SJ Br. 16.) But, *Morganroth* involved the Commissioner's refusal to revive a patent application on the ground that he lacked the authority to do so where an application was abandoned by failing to file an appeal from an adverse District Court ruling. 885 F.2d at 847. *Morganroth* is a case where the agency **disclaimed** authority under the relevant statute as compared to here where the PTO is **asserting** expanded authority. The PTO's reliance on *Centigram Commc'ns Corp. v. Lehman*, 862 F. Supp. 113 (E.D. Va. 1994) is similarly unavailing. (PTO SJ Br. 16.) *Centigram* involved a procedural rule relating to reviving patents abandoned due to unintentional failure to pay a maintenance fee, and further Congress "literal[ly] . . . grant[ed] the Commissioner the authority to reinstate *any patent* meeting those specific requirements." 862 F. Supp. at 117 (emphasis in original). In other words, in *Centigram*, "[t]he statute's plain language [left] no doubt that Congress squarely addressed this question." *Id.*

the Final Rules do not comport with statutory or case law. The PTO cites *Stevens v. Tamai* for the proposition that the PTO may “establish burdens of proof” (PTO SJ Br. 19-20), but *Stevens* merely condoned the PTO’s rule requiring the submission of a translation of a foreign language application when an applicant relies on the foreign language application to establish priority in an interference, 366 F.3d at 1332.

Fourth, in a last-ditch effort to rescue its rules, the PTO argues that the distinction between “substantive” and “procedural” rules is an irrelevant “false dichotomy.” (PTO SJ Br. 17.) Preliminarily, in the two years since it first published the proposed rules, the PTO has never asserted this “false dichotomy” argument. To the contrary, the PTO has repeatedly distinguished between “procedural” and “substantive” rulemaking and characterized the Final Rules as procedural. (*See* Ex. 1 at 46,830 (“The changes . . . do not change the substantive criteria of patentability . . . [and t]herefore, these rule changes involve interpretive rules, or rules of agency practice and procedure.”) (citations omitted); PTO TRO Opp. Br. 21-23.)

More importantly, the Federal Circuit clearly sees a difference between “procedural” and “substantive” rules, as it has unambiguously stated that the PTO lacks substantive rulemaking authority. *See, e.g., Merck*, 80 F.3d at 1549-50; *Brand*, 487 F.3d at 869 n.3. Indeed, the *amicus* law professors who support the PTO do not agree that such a “false dichotomy” exists: they begin their analysis by conceding that the PTO’s only rulemaking power is to “make regulations governing its *internal proceedings*.” (L. Profs. Br. 4 (emphasis added).) Moreover, the APA itself draws a distinction between “procedural” and “substantive” rules. 5 U.S.C. § 553(b).

In sum, the Final Rules are “inconsistent with law” and, therefore, exceed the PTO’s authority. *See infra* §§ II.B., II.C., and II.D.; (GSK SJ Br. 20-28).

B. The Arbitrary And Mechanical Limit On Continuing Applications In Final Rule 78 Is Contrary To Established Patent Law.

1. Final Rule 78 Is Inconsistent With The Plain Language Of Section 120.

Rule 78's arbitrary limit on continuing applications contradicts the plain language of section 120, which expressly states that a continuation application "shall" be given the benefit of the same filing date as the application to which it references, so long as the other requirements of Title 35 are satisfied. Although the PTO does not dispute this language (*see* PTO SJ Br. 21), it nevertheless asserts that it has the authority to impose "reasonable conditions" on continuation applications because section 120 allegedly "says nothing" on that issue, (*id.* 21-22). Section 120, however, is not silent and could not be more clear: if an application meets the formal requirements of section 120, then the PTO *shall* (*i.e.*, must) accord the application the benefit of the earlier filing date. The PTO is not at liberty to add to the requirements Congress created in section 120. *See Ry. Labor Execs. Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc) (text, structure, case law and 60-year history of Board recognizing limited authority justified invoking *expressio unius* canon). Rule 78's mechanical limit therefore contradicts the express language of section 120.

Contrary to the PTO's assertion, Rule 78 is not a "reasonable condition," but a hard limit. The PTO has made clear that it will deny a petition for a third continuing application in almost all circumstances. (*See* Ex. 1 at 46,769-77.)⁸ Neither the PTO nor the three *amici* who support it identified a single set of circumstances under which the PTO has indicated it will grant a petition

⁸ Moreover, the PTO's own ethical rules may bar GSK from even submitting a petition in the first instance, further evidencing that Final Rule 78 imposes a hard limit. (*See* GSK SJ Br. 22; Manbeck Decl. ¶¶ 40-42.)

to exceed Rule 78's limit of two continuing applications.⁹ Conversely, the PTO has gone so far as to indicate that it will refuse to accept justifications for filing additional continuations that the Federal Circuit expressly validated in *Symbol IV*. (See GSK SJ Br. 10, 21; Manbeck Decl. ¶¶ 32-35, 38.)

Further highlighting Rule 78's hard limit is the fact that the PTO will bar an applicant from obtaining additional continuing applications to submit claims to cover a competitor's product. (Ex. 1 at 46,775.) The three *amici* who support the PTO also complain about applicants who obtain additional continuing applications to submit claims to cover competitors' products. (Micron Br. 6; PPF Br. 10; L. Profs. Br. 14-15.) However, the Federal Circuit has unambiguously approved of applicants filing continuing applications for this purpose.

It should be made clear at the outset of the present discussion that there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application.

Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). Thus, Rule 78 substantively changes the law.

The PTO also manufactures a textual conflict between GSK's reading of section 120 and sections 112, 121, and 251 of the Patent Act. (See PTO SJ Br. 22-23.) Never mind that the PTO has applied these sections without any conflict for decades; there simply is no conflict, and the PTO does not cite a single case that supports its position. Instead, the PTO warps the Federal Circuit's pronouncement in *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046

⁹ For that same reason, the PTO's newly contrived argument that Final Rule 183 provides an "extraordinary circumstances" exception to Rule 78's hard limit is also without merit. (See PTO SJ Br. 25 n.12.) The PTO fails to identify a single set of circumstances that would satisfy that standard, further confirming that Final Rule 78 is a hard limit.

(Fed. Cir. 2002), that subject matter “disclosed but . . . not claim[ed is] dedicated to the public.” (PTO SJ Br. 22.) *Johnson & Johnston* expressly endorses filing continuing applications to claim disclosed but unclaimed subject matter and rejects the notion that there is a textual conflict:

A patentee who inadvertently fails to claim disclosed subject matter, however, is not left without remedy. Within two years from the grant of the original patent, a patentee may file a reissue application and attempt to enlarge the scope of the original claims to include the disclosed but previously unclaimed subject matter. 35 U.S.C. § 251 (2000). In addition, a patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. § 120 (2000) (allowing filing as a continuation application if filed before all applications in the chain issue). Notably, Johnston took advantage of the latter of the two options by filing two continuation applications that literally claim the relevant subject matter.

285 F.3d at 1055 (The two “continuation applications” that the Federal Circuit specifically endorsed are the second and third out of six that the applicants filed.); *see also Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1317 (Fed. Cir. 2007) (“It is recognized that an applicant can broaden as well as restrict his claims during the procedures of patent examination, and that continuing applications may present broader claims than were allowed in the parent.”) (citing *Symbol IV*), *cert. denied*, 128 S. Ct. 391 (2007). Thus, no conflict exists.

The PTO also mistakenly argues that the history of section 120 supports the purported textual conflict. (PTO SJ Br. 23-24 (citing *Woodbridge v. United States*, 263 U.S. 50 (1923) and *Webster Elec. Co. v. Splitdorf Elec. Co.*, 264 U.S. 463 (1924)).) First, as explained, there is no conflict. Second, the two cases the PTO cites merely concern prosecution laches. *See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 277 F.3d 1361, 1364 (Fed. Cir. 2002) (“*Symbol II*”) (identifying *Woodbridge* and *Webster Electric* as prosecution laches cases); *see also Symbol IV*, 422 F.3d at 1385 (same); *In re Bogese II*, 303 F.3d 1362, 1367 (2002) (same). Thus, the history of section 120 confirms that, for over a century, applicants have been permitted to file additional continuing applications so long as they did not run afoul of the doctrine of prosecution laches.

2. The Doctrine Of Prosecution Laches Does Not Save Rule 78.

The PTO asserts that the equitable doctrine of prosecution laches allows it to impose “reasonable conditions” on the number of continuing applications that any applicant may file. (See PTO SJ Br. 23-25.) Inexplicably, however, neither the PTO nor the *amici* who support it address *Symbol IV* in their briefs, the key case on the issue.¹⁰

Under *Symbol IV*, the prosecution laches doctrine applies *only* in egregious cases and *only* on a case-by-case basis. See *Symbol IV*, 422 F.3d at 1385; see also *Bogese III*, 303 F.3d at 1368 n.6, 1369; *Symbol II*, 277 F.3d at 1364. As the Federal Circuit court expressly warned:

There are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches, and the doctrine should be *used sparingly lest statutory provisions be unjustifiably vitiated*. The doctrine should be *applied only in egregious cases* of misuse of the statutory patent system.

¹⁰ In its manual governing internal procedures, the PTO acknowledged that the prosecution laches doctrine was limited to egregious circumstances, citing *Symbol IV*.

The Federal Circuit affirmed a rejection of claims in a patent application on the ground that applicant had forfeited his right to a patent under the doctrine of prosecution history laches for unreasonable and undue delay in prosecution. *In re Bogese*, 303 F.3d 1362, 1369, 64 USPQ2d 1448, 1453 (Fed. Cir. 2002) (Applicant “filed twelve continuation applications over an eight-year period and did not substantively advance prosecution when required and given an opportunity to do so by the PTO.”). >***While there are no firm guidelines for determining when laches is triggered, it applies only in egregious cases of unreasonable and unexplained delay in prosecution.*** For example, where there are “multiple examples of repetitive filings that demonstrate a pattern of unjustified delayed prosecution,” laches may be triggered. *Symbol Tech. Inc. v. Lemelson Med., Educ., & Research Found.*, 422 F.3d 1378, 1385, 76 USPQ2d 1354, 1360 (Fed. Cir. 2005) (Court discussed difference between legitimate reasons for refiling patent applications and refilings for the business purpose of delaying the issuance of previously allowed claims.).

PTO, Manual of Patent Examining Procedure (“MPEP”) § 2190 (8th ed. 2007) (emphasis added). The PTO goes so far as to require its examiners to “obtain approval from [their supervisors] before making a rejection on the grounds of prosecution history laches.” *Id.* The foregoing also demonstrates that *Bogese II* is a prosecution laches case properly read in the context of *Symbol IV*.

Symbol IV, 422 F.3d at 1385 (emphasis added). This is consistent with *Bogese II*'s pronouncement that the PTO lacks the ability to impose "a mechanical rule based on a misconstruction of the statutory requirements" and that each case should be decided on its facts. 303 F.3d at 1368 n.6, 1369. The Federal Circuit's *Symbol II*, *Bogese II*, and *Symbol IV* trilogy establishes that the PTO may reject applications based upon prosecution laches only in extreme situations on a case-by-case basis, not in Rule 78's mechanical and arbitrary manner.¹¹ See *Symbol IV*, 422 F.3d at 1385-86 (affirming the unenforceability of fourteen patents under the prosecution laches doctrine when "an 18- to 39-year time period had elapsed between the filing and issuance of the patents in suit"); *Bogese II*, 303 F.3d at 1369 (affirming a PTO rejection where "Bogese filed twelve continuation applications over an eight-year period and did not substantively advance prosecution of his application when required and given an opportunity to do so by the PTO"); see also *Novozymes A/S v. Genencor Int'l, Inc.*, 446 F. Supp. 2d 297, 333 (D. Del. 2006) (citing *Symbol IV* and finding no prosecution laches where the patent issued from a divisional application of a third continuing application and more than ten years after its effective filing date); *Kothman Enters., Inc. v. Trinity Indus., Inc.*, 455 F. Supp. 2d 608, 646 (S.D. Tex. 2006) ("[O]nly one district court (now affirmed by the Federal Circuit) has found prosecution laches, and in that case the delays were as long as 39 years.").

In short, as recognized over thirty years ago, the language of section 120 is "clear and unambiguous," and that imposing "a limit upon continuing applications is a matter of policy for

¹¹ The PTO's argument that *Bogese II* limited the holding of *Henriksen* is overbroad and, as articulated, incorrect. In *Bogese II*, the Federal Circuit recognized that it was bound by *Symbol II*'s finding that Congress' passage of section 120 did not foreclose the prosecution laches defense. 303 F.3d at 1367. Based on that binding precedent, the *Bogese II* court stated that *Henriksen* was limited only in that it did not suggest or imply that section 120 deprived the PTO of the ability to reject applications under the doctrine of prosecution laches. *Bogese II*, 303 F.3d at 1368 n.6.

the Congress.” *Hogan*, 559 F.2d at 604 & n.13 (citing *Henriksen*); *see also Henriksen*, 399 F.2d at 254 (There “is no statutory basis for fixing an arbitrary limit to the number of prior applications.”); *Ex Parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975) (“[T]he Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved.”).

C. Final Rule 114 Is Inconsistent With Section 132.

The PTO argues that it may impose a “reasonable” restriction on an applicant’s ability to file an RCE. (PTO SJ Br. 26-27.) The language of section 132(b), however, demonstrates the contrary: the PTO “*shall* prescribe regulations to provide for the continued examination of applications for patent *at the request of the applicant*.” (Emphasis added.) In using the word “shall” and the phrase “at the request of the applicant,” Congress manifested its intent that RCEs be unlimited, and that continued examination be at the discretion of the applicant, not the PTO. (*See Manbeck Decl.* ¶¶ 27-28.) Thus, section 132(b) does not permit the PTO to place mechanical limits on RCEs, “reasonable” or otherwise.

As it did in opposing GSK’s request for preliminary relief, the PTO again incorrectly describes new Rule 114 as one under which “an applicant who has received a final Office action may, as a matter of right, file one RCE.” (PTO SJ Br. 26.) This misrepresents the situation. Final Rule 114 is, in fact, much more limited in that it only allows an applicant to file one RCE *per application family*, contrary to the statutory language and clear congressional intent. Under Final Rule 114, “an applicant is permitted to file a *single* request for continued examination without a petition and showing in a *single application family*. An *application family* includes the initial application and its continuation or continuation-in-part applications.” (Ex. 1 at 46,737 (Final Rule 1.114(f)(1)) (emphasis added) (citation omitted).) By contrast, the plain language of section 132(b) allows for unlimited RCEs in the initial application, unlimited RCEs per

continuation application, and unlimited RCEs per continuation-in-part application. Thus, Final Rule 114 drastically limits the number of RCEs applicants to which applicants are entitled as a matter of right.

Chapter 12 of the Patent Act does not limit RCEs to one per application family as set forth in Final Rule 114; indeed, the phrase “application family” does not appear in Chapter 12. Rather, section 131 requires that the PTO conduct “an examination to be made of the application.” Section 132(a) requires that the PTO notify the applicant of any rejection or objection to “his application” and that if “the applicant persists in his claim for a patent . . . the application shall be reexamined.” Section 132(b) orders the PTO “to provide for the continued examination of applications for patent at the request of the applicant.” Read together, the statutes require the PTO to examine applications and provide for the continued examination of applications—not each application family. Further, upon enacting section 132(b), Congress indicated that the RCE provisions of section 132(b) apply to “all applications,” not just one application per patent application family. *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 to 1501A-561 (1999). Thus, Rule 114’s arbitrary limit is inconsistent with section 132(b) and must be vacated.

Realizing that there is no textual support for Rule 114’s arbitrary limit on RCEs, the PTO for the first time asserts that the Court should defer to the PTO’s substantive rule because section 132(b) provides the PTO with greater rulemaking authority than section 2(b)(2). (PTO SJ Br. 27.) Specifically, the PTO contends that section 132(b)’s directive that the PTO “prescribe regulations” to provide for RCEs gives the PTO a “sweeping grant of authority” to regulate RCEs beyond the powers listed in section 2(b)(2). (*Id.*) In directing that the PTO “prescribe regulations,” however, Congress merely ordered the PTO to promulgate regulations to allow for

the new RCE procedure it created in 1999. It did not grant the PTO authority beyond that set forth in section 2(b). Thus, the PTO's eleventh-hour invocation of this "sweeping grant of authority," not once mentioned in the 127-page Federal Register publication of the Final Rules, should be rejected.¹²

D. Final Rules 75 And 265 Are Inconsistent With The Patent Act.

1. Final Rules 75 And 265 Are Inconsistent With The Plain Language Of Section 112, Paragraph 2.

The PTO argues that it may limit the number of claims an applicant may submit. (PTO SJ Br. 27-29; *see also* Ex. 18 at A00434-35 (explaining that the PTO will "Limit Claims" in an attempt to improve efficiency); Ex. 20 at A07096 (assuming reduction in filings based on the claim limits).) The PTO's argument rests primarily on its faulty contention that the Final Rules are entitled to *Chevron* deference. As demonstrated above, however, no such deference is due.

¹² Even if section 132(b) provides the PTO with greater rulemaking authority than it possesses as a baseline matter, which the section does not, the PTO still acted arbitrarily and capriciously because it failed to provide any reasoned analysis for its departure from the PTO's initial rules regarding RCEs. When agencies change course, they must provide an explanation not only sufficient to justify adopting the change as if it had been writing on a clean slate, the agency must also explain why the change in course has been adopted. *See Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983) ("A 'settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress. There is, then, at least a presumption that those policies will be carried out best if the settled rule is adhered to.' Accordingly, an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.") (citation omitted)). When the PTO initially enacted regulations to provide for RCEs, it recognized that the RCE provisions of section 132(b) applied to "all applications" and that "an applicant . . . is not limited in the number of times" he can file an RCE. *See Request for Continued Examination Practice and Changes to Provisional Application Practice*, 65 Fed. Reg. 50,092, 50,095 (Aug. 16, 2000); *see also Changes to Application Examination and Provisional Application Practice*, 65 Fed. Reg. 14,865, 14,868 (Mar. 20, 2000) (interim rule). Now, years later, the PTO has adopted a new and completely inconsistent approach in Final Rule 114, without attempting to explain how its prior construction of the statutory language was in error. Accordingly, even if the PTO possessed broader rulemaking power pursuant to section 132(b), under *State Farm*, its inadequate analysis requires that the rule be vacated and remanded. *See also infra* § II.I.

See supra § I.A. Regardless, the claim limits in Final Rules 75 and 265 would fail under the first step of *Chevron* because the limits contradict the clear statutory language of section 112 of the Patent Act.

The PTO argues that section 112 does not prohibit the PTO from limiting the number of claims an applicant may seek. (PTO SJ Br. 28-29.) Specifically, it argues that nothing in section 112 prohibits it from requiring applicants who seek an arbitrary number of claims to submit “additional information” in the form of an ESD. (*Id.*) But, if an applicant does not comply with the ESD requirements, then the PTO will abandon the application. (Ex. 1 at 46,836 (Final rule 75(b)(3)).) Thus, what the PTO euphemistically describes as a requirement to disclose “additional information,” in fact alters substantive rights and threatens the loss of adequate patent protection.

By limiting the number of claims an applicant may seek, Final Rules 75 and 265 contradict the clear language of section 112, which expressly allows an applicant to file “one or more claims” as long as the claims “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2. It is well-established that “there is no statutory authority for rejecting claims as being ‘unnecessary.’ [Rather], *an applicant should be allowed to determine the necessary number and scope of his claims*, provided he pays the required fees and otherwise complies with the statute.”¹³ *Wakefield*, 422

¹³ Section 112, ¶ 2, however, permits the PTO to reject claims on a case-by-case basis for undue multiplicity, *i.e.*, when the number of claims obscures the invention such that they fail to particularly point out and distinctly claim the subject matter of the invention. *See, e.g., In re Flint*, 411 F.2d 1353, 1357 (C.C.P.A. 1969) (requiring that the PTO assess the propriety of the number of claims “on the basis of the relevant facts and circumstances in each individual case”) (quoting *In re Chandler*, 319 F.2d at 225); *In re Clark*, 97 F.2d 628, 631 (C.C.P.A. 1938) (“As we understand it, under the patent law and the prevailing Patent Office practice, an inventor, where it is difficult to express his invention in the form of claims, has the right to, and ordinarily for his own protection does, express the same invention in more than one claim. If by so doing

F.2d at 900 (emphasis added); *In re Chandler*, 319 F.2d 211, 225 (C.C.P.A. 1963). In fact, the PTO has conceded that “[t]he *patent statute* and rules of practice *do not limit* the number of claims (independent or dependent) that may be presented in an application.” (Ex. 24 at A07333.) (emphasis added). Hence, nothing in the Patent Act authorizes or allows the PTO to impose mechanical rules limiting the number of claims an applicant may seek.

Also, relying on dicta in *In re Rubinfeld*, 270 F.2d 391, 395 (C.C.P.A. 1959), the PTO argues that Final Rules 75 and 265 are valid because they are less restrictive than a rule limiting design patents to only one claim. (PTO SJ Br. 28-29.) *Rubinfeld*, however, rests on a since-discarded analytical framework regarding deference.¹⁴ Moreover, *Rubinfeld* is distinguishable because design patents are fundamentally different from utility patents. See *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1354-55 (Fed. Cir. 2005) (rejecting argument based on design patent law because it bore no relation to the utility patent question at issue); 8 Donald S. Chisum, *Chisum on Patents* § 23.01 (2007) (“A design patent fundamentally differs from a utility patent.”); compare 35 U.S.C. § 101 with 35 U.S.C. § 171. Courts have long recognized that, unlike utility patents, a design patent requires only a single claim because the patent specification’s drawings determine the scope of protection, not the claim language. See *Tecumseh Prods. Co. v. Briggs & Stratton Corp.*, 295 F. Supp. 2d 902, 909 (E.D. Wis. 2003) (“Unlike a utility patent, which is defined by a series of numbered claims, a design patent has only one claim which is defined by the accompanying figures.”); *Minka Lighting, Inc. v.*

he more clearly defines his invention and does not by undue multiplicity obscure the same, he is acting within the rights granted and the duties required by the patent laws.”).

¹⁴ The court in *Rubinfeld* deferred to the single claim design patent rule because it found no “clear conflict” between the rule and section 112. 270 F.2d at 395. That test, however, is no longer the law as it was effectively overruled by *Adams Fruit* and *Merck*, which together establish the modern framework for assessing deference to PTO rulemaking that exceeds Congress’ delegation of authority to the agency. See *supra* § II.A.

Craftmade Int'l, Inc., No. 00-CV-0888, 2001 WL 1012685, at *1 (N.D. Tex. Aug. 20, 2001) (“Unlike utility patents, the heart and soul of a design patent is the content of the drawing.”); *see also Rubinfield*, 270 F.3d at 395-96 (explaining that “no useful purpose could be served by the inclusion of more than one claim in a design application or patent”). Recognizing this fundamental characteristic, the *Rubinfield* court explained that one broad claim to “[t]he ornamental design for a floor waxer substantially as shown’ would afford exactly the same degree of protection to appellant . . . as would the three claims” originally sought and rejected. 270 F.3d at 396. In sharp contrast, utility patent protection extends only to that which is expressly claimed. *See Datamize*, 417 F.3d at 1354 (recognizing that the scope of a utility patent “is defined by the patent’s written claims”). In light of this, the PTO’s reliance on *Rubinfield* to justify its limits on utility patent claims is wholly misplaced.¹⁵

2. Final Rule 265 Unlawfully Requires An Applicant To Conduct A Prior Art Search And Unlawfully Shifts The Burden Of Prosecution From The PTO To The Applicant.

The PTO also argues that it may require submission of an ESD “to aid the patent examiner in determining whether the applicant is, in fact, entitled to a patent under the law.” (PTO SJ Br. 29.) By requiring applicants to affirmatively search for information beyond that which they already possess and examine their own application in the first instance, the ESD unlawfully shifts the examination burden onto applicants. (*See* Ex. 1 at 46,842 (Final Rule 265).) “As a general rule, there is no duty to conduct a prior art search, and thus there is no duty to disclose art of which an applicant could have been aware.” *Frazier v. Roessel Cine Photo Tech., Inc.*, 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting *FMC Corp. v. Hennessy Indus., Inc.*,

¹⁵ The PTO’s summary judgment brief is its first reference to *Rubinfield*, including the 127-page Federal Register notice. The only pertinent references to design patents in the lengthy notice expressly state that the new rules would not apply to design patents. (Ex. 1 at 46,731, 46,839.)

836 F.2d 521, 526 n.6 (Fed. Cir. 1987)). Because the PTO lacks the authority to require an applicant to conduct a prior art search, the ESD's preexamination search requirement is invalid.¹⁶

The ESD's patentability examination requirement also contravenes the Patent Act, which mandates that the PTO, not applicants, examine applications. Section 131 provides that the "Director *shall cause an examination to be made* of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefore." (Emphasis added); *see also In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998) (stating that absent "a proper *prima facie* case of obviousness, an applicant . . . is entitled to a patent"). Further, although ignored by the PTO, the Patent Act places the initial burden of proof on the PTO by requiring it to first prove that an applicant is not entitled to a patent and to explain the reasons why. Indeed, sections 102 and 103 provide that "[a] person *shall be entitled to a patent unless*" the claimed invention lacks novelty or is obvious in view of the prior art. (Emphasis added); *see also In re Warner*, 379 F.2d 1011, 1016 (C.C.P.A. 1967) (stating that "the precise language of 35 U.S.C. § 102 that '(a) person shall be entitled to a patent unless,' . . . clearly places a burden of proof on the Patent Office"). Thus, as the Federal Circuit and its predecessor court explained, the Patent Act unambiguously places the burden of proof on the PTO to establish a *prima facie* case that an applicant is not entitled to a patent. Only *after* the PTO demonstrates a *prima facie* case of unpatentability does the burden then shift to the applicant to rebut that showing. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, the burden of

¹⁶ The fact that Congress has considered, but has yet to grant the PTO authority to require patent applicants to carry out such searches further illustrates that the PTO currently lacks such authority. (See Ex. 17 at § 123.)

coming forward with evidence or argument shifts to the applicant.”). Here, because Final Rule 265 forces applicants to justify patentability before the PTO demonstrates a *prima facie* case of unpatentability, that requirement is unlawful.¹⁷

In short, the PTO has no authority, statutory or otherwise, to set arbitrary claim limits, to require a preexamination prior art search, or to shift the burden of examination to the applicant. As a result, Final Rules 75 and 265 must be vacated.

E. The ESD’s Preexamination Search Requirement Is Incomprehensibly Vague And Fails To Provide Sufficient Notice As To How To Comply.

The PTO asserts that GSK cannot prevail on its vagueness claim because: (1) Final Rule 265 is immune from the void-for-vagueness doctrine; and (2) Final Rule 265 is not vague. Neither assertion withstands scrutiny.

1. The Final Rules Must Be Stricken Under The Fair Notice Doctrine.

The PTO asserts that GSK has no due process claim under the “void for vagueness” doctrine because that doctrine only relates to regulations defining prohibited conduct. (PTO SJ Br. 52-54.) In a nutshell, the PTO posits that an agency may promulgate any regulation, no

¹⁷ The PTO’s cited authority does not support the proposition that the PTO may require applicants to disclose additional information. Instead, the PTO’s “authority” deals with information already known by and available to the applicant. See 37 C.F.R. § 1.56 (requiring applicants to disclose all “known” information material to patentability); *id.* § 1.105 (identifying categories of information known and available to applicants that examiners may require be disclosed); *Hyatt v. Dudas*, 492 F.3d 1365, 1368 (Fed. Cir. 2007) (recognizing that the PTO must first establish a *prima facie* case for rejection before requiring the applicant to disclose known information relevant to patentability); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351-52 (Fed. Cir. 2005) (affirming the district court’s finding of inequitable conduct because, among other things, the applicant actually knew of the prior art and failed to disclose it to the PTO); *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1280, 1282-83 (Fed. Cir. 2005) (concerning the PTO’s authority to require disclosure of information within the applicant’s possession that the examiner deems relevant to patentability). Notably, none of these references authorizes the PTO to impose burdensome new prior art searches and patentability analyses on applicants, let alone to do so before the PTO establishes a *prima facie* case of unpatentability.

matter how vague, so long as it does not prohibit conduct. Due process, however, is not so narrow. It is well-settled that “[t]raditional concepts of due process incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.” *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987). The PTO ignores the fair notice doctrine, despite this Court’s prior reliance on the doctrine and the PTO’s own invocation of the doctrine. *See GlaxoSmithKline*, 511 F. Supp. 2d at 667-68 (citing *Freeman United Coal Mining Co. v. Fed. Mining Safety & Health Review Comm’n*, 108 F.3d 358, 362 (D.C. Cir. 1997)); (PTO SJ Br. 55 (quoting *Freeman United* when stating that regulations must provide “fair warning” of what they prescribe).)

Cases finding violations of due process under the fair warning doctrine are legion, even where the regulations at issue did not prohibit conduct. *See, e.g., Satellite Broad. Co.*, 824 F.2d at 2-4 (prohibiting the enforcement of a vague regulation, as here, relating to application requirements); *see also United States v. Chrysler*, 158 F.3d 1350 (D.C. Cir. 1998) (barring vehicle recall where the agency regulation was not penal, but enforced a certification requirement—a privilege, not a right); *United States v. Hoechst Celanese Corp.*, 128 F.3d 216 (4th Cir. 1997) (applying fair notice doctrine to an *exemption* from a standard regulating benzene); *cf. Cole v. Young*, 351 U.S. 536, 556 (1956) (Executive Order’s “failure to state explicitly what was meant is the fault of the Government. Any ambiguities should therefore be resolved against the Government.”); *Freeman United Coal Mining*, 108 F.3d at 362 (“[T]o

satisfy constitutional due process requirements, regulations must be sufficiently specific to give regulated parties adequate notice of the conduct they require or prohibit.”).¹⁸

The key inquiry is not whether conduct is prohibited, compliance mandated, or benefits sought, but rather the character of the risk posed to the regulated entity by a vague standard. *Chrysler*, 158 F.3d at 1354 (The “simple truth is that there is no real difference between ‘violating’ a regulation, for which notice is required, and ‘not complying’ with a regulation.”). ***Application requirements*** that fail to provide fair notice to applicants cannot be invoked to deny applications. *Satellite Broad.*, 824 F.2d at 3 (holding that the “the dismissal of an application . . . is a sufficiently grave sanction to trigger this duty to provide clear notice”); *see also Radio Athens, Inc. v. FCC*, 401 F.2d 398, 404 (D.C. Cir. 1968) (denial of application overturned for failure to provide adequate notice of requirements). Here, there is a palpable risk to GSK and others of a “penalty”: failure to comply with Final Rule 265’s incomprehensible requirements will result in the abandonment of the application, *i.e.*, loss of property rights. That risk invokes the protections of due process. *See Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1328 (D.C. Cir. 1995) (“Due process requires that parties receive fair notice before being deprived of ***property***.”) (emphasis added).¹⁹

¹⁸ Numerous other circuits have adopted the fair notice doctrine. *See United States v. Trident Seafoods*, 60 F.3d 556, 559 (9th Cir. 1995); *D&W Food Ctrs., Inc. v. Block*, 786 F.2d 751, 757-58 (6th Cir. 1986); *Bethlehem Steel Corp. v. OSHRC*, 573 F.2d 157, 161-62 (3d Cir. 1978); *Diamond Roofing Co. v. OSHRC*, 528 F.2d 645, 649 (5th Cir. 1976).

¹⁹ The PTO relies heavily on *Nyeholt v. Sec’y of the Veterans Affairs*, 298 F.3d 1350, 1356 (Fed. Cir. 2002) to support its assertion that due process protections apply only to “prohibitions of conduct” and not the regulations at issue here. (PTO SJ Br. 53.) *Nyeholt*, however, addressed a veteran’s allegation that a regulation, which dictated the manner in which doctors rated liver ailments for determining benefits, was void-for-vagueness. 298 F.3d at 1357. Thus, the facts of *Nyeholt* bear no relation to this case. Nor did the court address the fair notice doctrine. Finally, as the court stated, *Nyeholt* had not provided any case law and the court was unaware of any suggesting that a regulation “that does not purport to define the lawfulness or unlawfulness of either conduct or speech can be challenged under the void-for-vagueness doctrine.” *Id.* at 1356.

2. Final Rule 265 Is Fatally Vague.

While regulations do not require “exact direction” (*see* PTO SJ Br. 57), they do need to inform a reasonably prudent person how to comply. A reasonably prudent person cannot comply with the ESD requirement, a point the PTO does not dispute. Rather, the PTO asserts that “[t]he rule cannot . . . be read in isolation.” (*Id.* at 55.) The PTO relies on a litany of extrinsic sources to cure the facial vagueness of the ESD’s preexamination search requirement. (*Id.* at 55-57.) The PTO’s reliance on such guidance, however, demonstrates that Final Rule 265 is vague and fails to provide fair notice.

GSK has already explained the intrinsic error the PTO makes when it invokes sources that are not themselves law. (*See* GSK SJ Br. 29-30 (demonstrating that guidelines, the MPEP, and the like are not law and so cannot bind regulated parties)); *see also* *GlaxoSmithKline*, 511 F. Supp. 2d at 668 (“[A]ny guidance documents generated by the PTO outside of the notice and comment rulemaking process violate the Administrative Procedure Act.”). But even when the documents are considered, it corrupts the notion of fair process when the envisioned process entails a lengthy slog through an endless series of “guidance” documents that “may” (or may not) lead to the creation of a successful ESD. (*See* GSK SJ Br. 30-31 (noting the PTO’s equivocations on the search required and the possibility of ultimate success).)²⁰

By contrast, GSK has provided several cases herein finding the contrary, and has explained how Final Rule 265 regulates applicants’ conduct.

²⁰ The curatives identified by the PTO—(a) the opportunity to amend a rejected ESD to cure its deficiencies within two months or (b) the abandonment of claims so that the application contains no more than 5/25 claims—are instead bitter medicine (*See* PTO SJ Br. 57 (citing Final Rule 265(e)).) First, that an applicant *may* be able to cure deficiencies through amendment says nothing about whether the regulation is or is not unduly vague in the first instance, and there are no cases that require the applicant to learn the hard way when faced with a defective regulation. Second, the suggestion that one should abandon claims in order to avoid the ESD’s incomprehensible search requirement is unjustifiable. When the agency promulgates a

In any event, the extrinsic sources invoked do not sufficiently explain how one can with any degree of certainty comply with Final Rule 265. GSK has explained why the invoked sources fail to provide the requisite notice required. (GSK SJ Br. 30-31.) Notably, the PTO's own Patent Public Advisory Committee agrees, having stated, "[t]here is no rule of reason applied to foreign patent searching and non-patent literature searching." (Ex. 25 at A01295.) And where "different divisions of the enforcing agency disagree about their meaning," it is "unlikely that regulations provide adequate notice." *Gen. Elec. Co.*, 53 F.3d at 1332; *see also Rollins Envtl. Servs. (NJ) Inc. v. EPA*, 937 F.2d 649, 653 (D.C. Cir. 1991) ("When the agency itself is uncertain of the meaning of its regulation . . . it is arbitrary to find the regulation 'clear.'"). Given the importance of Final Rule 265 in the overall scheme—applicants are cut off from their right to file more than five independent and twenty-five total claims, absent compliance—its intrinsic vagueness and failure to adequately warn require its invalidity. *See Satellite Broad.*, 824 F.2d at 4 (Where agency rule invoked "to cut off a party's right, it must give full notice of its interpretation."); *see also Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1028 (D.C. Cir. 2000) (setting aside guidance document as procedurally defective because it was an improper attempt at agency rulemaking).

F. The Final Rules Are Retroactive And Unlawful Under *Bowen*.

The PTO argues that the Final Rules are not retroactive because (i) they are procedural; (ii) they do not impair applicants' rights; and (iii) they do not impose new duties with respect to completed transactions. (PTO SJ Br. 39-45.) These arguments run counter to the express reason that the PTO provided for promulgating the rules—to reduce the *backlog* of more than 700,000

regulation that unfairly places the regulated entity's property at risk, due process requires the *agency*, not the *entity*, to adjust its behavior.

unexamined patent applications pending before the PTO. (*See* TRO Hr’g Tr. 51:5-22.) The PTO’s arguments also fail to withstand scrutiny.²¹

1. The Retroactive Effect Of The Final Rules Is Not Diminished By Characterizing The Rules As “Procedural.”

The PTO argues that the Final Rules are not retroactive because they are “procedural.” (PTO SJ Br. 39-40.) While the Final Rules are not “procedural,” *see supra* section I.A., the Supreme Court has, in any event, rejected the PTO’s formalistic view of retroactivity, *see Martin v. Hadix*, 527 U.S. 343, 359 (1999) (In *Landgraf*, the Court “took pains to dispel the ‘suggest[ion] that concerns about retroactivity have no application to procedural rules.’”) (quoting *Landgraf v. USI Film Prods.*, 511 U.S. 244, 275 n. 29 (1994)).²² Instead of formalism, the Supreme Court has explained that the retroactivity inquiry “demands a *commonsense, functional* judgment about ‘whether the new provision attaches new legal consequences to events completed before its enactment.’” *INS v. St. Cyr*, 533 U.S. 289, 321 (2001) (quoting *Martin*, 527 U.S. at 357-58 and *Landgraf*, 511 U.S. at 270) (emphasis added). That judgment “should be informed and guided by ‘familiar considerations of fair notice, reasonable reliance, and settled expectations.’” *Id.* (citing *Martin* and *Landgraf*). Those considerations reveal that the Final Rules are unduly retroactive, as set forth below.²³

²¹ No *amicus* brief supports the PTO’s retroactivity positions. Indeed, the only *amicus* that mentioned retroactivity felt compelled to make clear that it was *not* taking a position on the issue of retroactivity. (*See* L. Profs. Br. 2 n.1.)

²² *See also Brown v. Angelone*, 150 F.3d 370, 373 (4th Cir. 1998) (“[T]here is nothing talismanic about identifying a rule as procedural if its application results in genuinely retroactive effects.”); *Church v. Attorney Gen. of Va.*, 125 F.3d 210, 212-13 (4th Cir. 1997) (Despite procedural nature of change, the increased fee for filing of appeals could not be applied retroactively.).

²³ *Combs v. Comm’r of Soc. Sec.*, 459 F.3d 640 (6th Cir. 2006) is not to the contrary. (*See* PTO SJ Br. 39-40.) There, the plaintiff challenged a change made to one step of the process used to adjudicate disability eligibility. *Combs*, 459 F.3d at 643-45. The Sixth Circuit explained that the plaintiff could show no reliance, or disability, caused by the regulatory change. *Id.* at 646. The

2. The Final Rules Would Impair Rights Applicants Possess Under The Current Patent Regime.

As GSK explained in its opening summary judgment brief, the PTO may not alter by fiat the bargained-for exchange of trade secret rights for the protections afforded by existing patent laws. (GSK SJ Br. 32-33.) The PTO counters that the Final Rules are not retroactive because they do not impair “vested rights” in pending applications. (PTO SJ Br. 40-43.) While *Landgraf* makes clear that this is a false restriction, *see* 511 U.S. at 275 n.29, the PTO is wrong that GSK lacks such rights, *see infra* § II.G.1. Under the current regime, applicants have entered into bargained-for exchanges with the PTO—the *quid pro quo* of constitutionally protected trade secrets, in exchange for the full spectrum of protection provided by the existing patent system. (*See* GSK SJ Br. 32-33.) Applicants relied on the rules in place when they filed their applications and began to prosecute their claims. The Final Rules, however, retroactively alter the bargain on which GSK and others relied upon when surrendering their trade secret rights for patent protection.

The PTO initially invokes a host of non-patent cases to argue that there are no cognizable rights in patent applications. (PTO SJ Br. 40-42.) All of these cases suffer from the same deficiency: none involve a similar bargained-for exchange of vested property rights for inalterable protections afforded by Congress. *See, e.g., BellSouth Telecomm., Inc. v. Southeast Tel., Inc.*, 462 F.3d 650, 664 (6th Cir. 2006) (No exchange of property right for government benefit sought: “Southeast did not give up or sacrifice anything in reliance on the FCC rule then

opposite is true here. GSK and other parties relied on the patent rules in place when they filed their applications and began to prosecute their claims. They determined how much information about their inventions to disclose and claim, or not claim, based on the current (threatened) regime. They made these decisions based on settled expectations that the PTO would not promulgate *ultra vires*, regulatory rules overriding Congress’ requirements.

in place. Applying the current law to Southeast's application, in other words, would not upset the basis of any *quid pro quo* that Southeast had previously entered into.”²⁴

The Supreme Court highlighted the issue of retroactivity in the bargained-for exchange context in *INS v. St. Cyr*, 533 U.S. 289 (2001). There, the plaintiff challenged, on retroactivity grounds, statutory changes that eliminated his ability to seek waiver of deportation by the Attorney General. Those changes took effect *after* he had accepted a plea bargain with the expectation that such relief could be available. Because the plea agreements “involve[d] a *quid pro quo* between a criminal defendant and the government,” *id.* at 321, in which a waiver of “constitutional rights (including the right to a trial),” had been *exchanged* for a “perceived benefit,” the change in law could not be applied retroactively, *id.* at 322. The same type of rights-for-benefit exchange risks abrogation here by the Final Rules. (*See generally* AIPLA SJ Br. (demonstrating the potential loss of past, present, and future intellectual property rights and investments brought about by the Final Rules); Manbeck Decl. ¶ 53.)

The PTO's older cases discussing patent applications are also inapt. (PTO SJ Br. 41-42.) The bulk of those cases long predate the Patent Act, subsequent amendments, and controlling Supreme Court precedent that reject the notion that there are no property rights affiliated with patent applications. *See* 35 U.S.C. §§ 154(d), 261; *see also infra* § II.G.1. Further, all but two of the cases predate *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), the Supreme Court's most recent pronouncement that intellectual property is protected property under the Takings Clause.

²⁴ *See also Pine Tree Med. Assocs. v. Sec'y of Health & Human Servs.*, 127 F.3d 118 (1st Cir. 1997) (no tradeoff; concerned a health care provider's bare desire to have a certain population be deemed “medically underserved” under criteria in place when application was first made); *Chadmoore Commc'ns, Inc. v. FCC*, 113 F.3d 235 (D.C. Cir. 1997) (no tradeoff; applicant merely sought to avail itself of longer time period for build-out of stations that had been available under prior regulatory regime); *Bergerco Canada, Div. of Conagra, Ltd. v. Treasury Dep't*, 129 F.3d 189 (D.C. Cir. 1997) (no tradeoff; firm merely sought to have the government grant a license under less stringent standards than in place at the time of application).

Under *Ruckelshaus*, patent applications are constitutionally protected property. *See infra* § II.G.1. As such, the PTO’s case law is irrelevant.²⁵

The PTO misses the point by arguing that GSK’s retroactivity claim “prove[s] too much,” because if accepted, the PTO “would never be able to amend its rules because some patent applications would always be ‘mid-stream.’” (PTO SJ Br. 42 (emphasis in original)). While it is true that there may always be applications pending, that does not alter the fact that the PTO may not issue rules that upset the basic *quid pro quo* by applying the Final Rules to and eviscerating rights in those *pending* applications. As the PTO itself concedes, the retroactivity of the Final Rules can be cured merely by “applying [them] only to future-filed applications.” (PTO SJ Br. 45 n.27.)²⁶ The same holds true for any other rules that the PTO might pass.

Finally, the PTO’s contention that GSK extinguished its own intellectual property rights “by failing to ask the USPTO to maintain its applications in confidence” and seeking patent protection abroad is a red herring.²⁷ (PTO SJ Br. 43.) GSK sacrificed its trade secrets in

²⁵ While *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 935 F.2d 1263 (Fed. Cir. 1991), is post-*Ruckelshaus*, the court did not address the issue of patent applications as constitutionally protected property or cite *Ruckelshaus*. The court in *Bruno Independent Living* likewise did not deal with retroactivity.

²⁶ The PTO argues that the proper remedy if the Final Rules are found to be retroactive is to construe the regulations as applying only to future-filed applications. (*See* PTO SJ Br. 45 n.27.) But that is a remedy the PTO can only adopt for itself, after remand. The PTO’s argument to the contrary conflates judicial review of statutes and of regulations. Courts must “remand to the agency for additional investigation or explanation” when the agency’s analysis is incomplete, after any flawed basis for agency action is removed. *INS v. Orlando Ventura*, 537 U.S. 12, 16 (2002) (per curiam) (quoting *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985)). Here, because the PTO designed the Final Rules to solve the significant backlog problem, there is substantial doubt that the PTO would have adopted these rules if the PTO could not apply them retroactively. Hence, the regulations must be vacated in their entirety and remanded.

²⁷ Notably, this is the first time the PTO has proffered such a theory. As such, in addition to being meritless, this argument must be ignored because agencies may not rely on the *post hoc* rationalizations of their counsel. *See Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156,

exchange for the full spectrum of protection afforded under the current system, including the ability to seek patent protection abroad. That *quid pro quo* was in no way conditioned on seeking only domestic patent protection. Further, relying on the current system, GSK and others allowed the PTO to publish their applications, disclosing trade secrets to the public but at the same time gaining valuable provisional rights in the published claims. *See* 35 U.S.C. § 154(d). Now, after GSK and others have reasonably relied on the current system, the PTO seeks to implement new rules that will strip applicants of their rights under that system.

3. The Final Rules Unlawfully Impose New Duties With Respect To Completed Transactions.

The PTO argues that the Final Rules do not impose “new duties with respect to completed transactions.” (PTO SJ Br. 43-44.) Notably, the PTO makes no attempt to dispute that the Final Rules impose new and onerous duties, a point that is, in any event, inarguable. (Manbeck Decl. ¶¶ 27-28, 32-34, 38, 40, 45-46, 48 (describing applicants’ new duties).) Instead, it argues that no “transactions already completed” are at issue here. (PTO SJ Br. 43-44.) But that argument rests once more on its preference for rank formalism over the functional approach mandated by the Supreme Court. (*Compare* PTO SJ Br. 43 (citing dictionary definition of “transaction”) *with Martin*, 527 U.S. at 357-58 (“The inquiry into whether a statute operates retroactively demands a *commonsense, functional judgment . . .*”) (emphasis added).)

The PTO argues that the filing of an initial application is not a completed transaction. (PTO SJ Br. 43.) The PTO is wrong (even as a formalistic matter) and, in any event, its myopic view ignores the fact that: (i) the applicant “voluntarily surrender[s] its property rights in exchange for a guarantee from the PTO that it will have a ‘full and fair opportunity to seek a

168-69 (1962); *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *In re Sang Su Lee*, 277 F.3d 1338, 1345-46 (Fed. Cir. 2002).

spectrum of patent protection adequate to protect [its] investments,” *see GlaxoSmithKline*, 511 F. Supp. 2d at 667; (ii) the applicant gains valuable property rights, including, for example, the right to assign the application, *see* 35 U.S.C. § 261; and (iii) the application filing sets the “priority date” of the application, which in turn limits the universe of prior art that may be used against the application (*see* APLA SJ Br. 17-18). The PTO also ignores that the publication of a patent application defines a completed transaction because both the public and the applicant are impacted: the public gets access to former trade secrets, and the applicant receives valuable provisional rights under section 154(d). (Manbeck Decl. ¶ 53.) That patent prosecution is an “iterative exchange” does not detract from these already completed transactions. (*See* PTO SJ Br. 43-44.)

The PTO finally argues that even if the filing of the application is a completed transaction, “the Final Rules do not render invalid any action taken by applicants before the effective date of the rules.” (PTO SJ Br. 44 (citation omitted).) This misstates the test, which under *Landgraf*, looks for the “impairment” of rights or the imposition of new legal duties, not the complete invalidity of prior actions. As stated above, there is no dispute that the Final Rules impose new duties. Consequently, the Final Rules are impermissibly retroactive.²⁸

²⁸ That some parties may theoretically be able to run the gauntlet of steps required to avoid the loss of rights in disclosed but as-yet-unclaimed inventions does not alter the *retroactivity* inquiry. GSK and others have elsewhere explained why the range of policies that the PTO also adopted in the Final Rules—like restriction requests, the petition and showing under the “could not have been” standard, the filing of an ESD—are nearly, if not totally, insurmountable. The notion that the PTO can survive the retroactivity analysis because it has created processes to take the sting out of the Rules’ retroactive effect is a proposition without legal or logical support.

G. The PTO's Failure To Adequately Consider The Final Rules' Taking Of Constitutionally Protected Property Rights In Patent Applications Was Arbitrary, Capricious, And Contrary To Law.

1. Property Rights Or Property Interests Clearly Exist In Patent Applications.

The PTO argues that patent applications do not confer cognizable property rights. (PTO SJ Br. 45-46.) In doing so, the PTO relies on antiquated case law that the Supreme Court abrogated in *Ruckelshaus*, and fails to address *Ruckelshaus* and sections of the Patent Act that expressly provide property rights in patent applications.²⁹ (See PTO SJ Br. 41-42, 45-46; GSK SJ Br. 34-35 & n.7 (distinguishing the PTO's old line of cases).) Controlling authority, which the PTO wholly ignores, confirms that patent applications are constitutionally protected property.

In *Ruckelshaus*, the Supreme Court held that trade secrets are property protected by the Takings Clause because “[t]rade secrets have many of the characteristics of more tangible forms of property.” 467 U.S. at 1002-04. Like other protected property, trade secrets can be transferred and assigned, form the *res* of a trust, and pass to a trustee in bankruptcy. *Id.* Similarly, patent applications, which applicants obtain in the *quid pro quo* bargain for disclosing their trade secrets, contain key characteristics of protected property. (Manbeck Decl. ¶ 21.) Under the Patent Act, such applications are transferable and assignable, *see* section 261, and can support provisional rights to collect damages after publication, *see* section 154(d). Moreover, under pertinent case law, patent applications can: form the *res* of a trust, *see, e.g., Conway v. White*, 292 F. 837, 843 (2d Cir. 1923); pass to the trustee in bankruptcy, *see, e.g., Keen, Inc. v.*

²⁹ Even though GSK has relied upon *Ruckelshaus* to support its takings claim since the filing of the complaint in this litigation, the PTO offers no excuses for not addressing it. Rather, it cites to two new, but irrelevant cases—*Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 935 F.2d 1263 (Fed. Cir. 1991) and *Boyden v. Comm’r of Patents*, 441 F.2d 1041, 1043 (D.C. Cir. 1971). (PTO SJ Br. 41, 42, 45.) Neither case concerned the issue of patent applications as protectable property. Nor did *Exxon*, the only case to come after *Ruckelshaus*, even mention *Ruckelshaus*.

Gecker, 264 F. Supp. 2d 659, 662-63 (N.D. Ill. 2003); and constitute taxable property, *Winchester v. Comm’r*, 27 B.T.A. 798, 801 (1933). (See GSK SJ Br. 34; Manbeck Decl. ¶ 21.)

2. The PTO Acted Arbitrarily And Capriciously In Failing To Sufficiently Address Takings Issues During Rulemaking.

The PTO next argues that any complaint by GSK about changes in patenting *procedures*, rather than a specific deprivation of a proven patent, is not actionable under the Takings Clause, citing a string of irrelevant cases. (See PTO SJ Br. 46-47.) The PTO misapprehends the nature of GSK’s takings challenge. GSK’s Takings Clause challenge is not based on a due process violation. Rather, GSK raises an administrative-law based takings challenge, contending that during the rulemaking process, the PTO failed to sufficiently and correctly address the serious takings risks that the Final Rules raise. (See Am. Compl. ¶¶ 145-53.) As established above, patent applications are protectable property rights. The Final Rules threaten to destroy those rights. Basic administrative law requires that the PTO appreciate the nature of those rights and have a proper understanding of the *quid pro quo* of trade secrets exchanged for ultimate patent protection. See, e.g., *Nat’l Wildlife Fed’n v. ICC*, 850 F.2d 694, 705-08 (D.C. Cir. 1988) (remanding the ICC’s “prematurely” “truncate[d]” analysis of takings issues).

The PTO was well aware of the serious takings risks. (See, e.g., Ex. 1 at 46,828 (“Several comments argued that . . . the new requirements would constitute a taking by the Federal Government.”).) But it offered only conclusory statements that do not remotely satisfy the agency’s burden to approach takings issues arising in rulemakings with the gravity they deserve and require. (See *id.* at 46,834 (bare-bones, one-sentence conclusion that the Final Rules do not create takings pursuant to Executive Order 12,630).) Thus, the PTO failed in its basic duties to comply with administrative law. See *Prof’l Pilots Fed’n v. FAA*, 118 F.3d 758, 771

(D.C. Cir. 1997) (A court may not “sanction agency action when the agency merely offers conclusory and unsupported postulations in defense of its decisions.”).

The PTO’s consistent defense in this litigation has been that patent applications have no attributes of property. The PTO is wrong—*i.e.*, patent applications are protectable as property rights or interests—hence, its takings analysis is wrong. Faulty analysis of important constitutional issues necessarily constitutes arbitrary and capricious rulemaking that must be vacated and remanded. *See* 5 U.S.C. § 706(2); *Nat’l Wildlife Fed’n*, 850 F.2d at 708 (vacating an agency’s regulation for insufficient and legally misinformed analysis of takings issues); *see also State Farm*, 463 U.S. at 43. Hence, the PTO’s Final Rules cannot stand.

3. The PTO’s Arguments Show It Improperly Refused To Undertake Analysis Under The *Lucas* Category Of Takings And That It Arbitrarily And Capriciously Analyzed *Penn Central* Balancing Issues.

The PTO argues that this case involves neither a physical taking, nor a taking sufficient to satisfy *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019-20 (1992). (*See* PTO SJ Br. 48-49 & n.29.) Hence, the PTO argues that the only category of takings analysis relevant to GSK’s case relates to regulatory takings, judged by the multi-factor balancing test in *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104 (1978).

The PTO is wrong. The *Lucas* category is relevant here. That category classifies as a *per se* taking any regulatory taking that destroys 100 percent of a particular element or parcel of property. Here, for example, the Final Rules limit continuing applications. *See supra* § II.B. As applied to pending patent applications, the limit on continuing applications will deny patents to patentable inventions that would otherwise constitute property. Any new continuing application involves a separate piece of property, 100 percent of which will be taken if the PTO denies the filing.

Additionally, GSK has easily shown that the PTO has not adequately considered the *Penn Central* regulatory takings factors in connection with the Final Rules. First of all, since the PTO failed to appreciate the issues involved in surrendering trade secret property rights under *Ruckelshaus*, and because the PTO flatly denies that patent applications are property rights or interests, it cannot possibly have correctly considered application of the three-part *Penn Central* test. *Penn Central* requires balancing: (1) the character of the governmental action affecting property; (2) the economic impact of the effects on the regulated parties; and (3) whether the regulated parties' property interests were protected by reasonable investment-backed expectations. *See Penn Cent.*, 438 U.S. at 124. Each of the factors involves understanding the precise nature of the property rights at issue *before* the question of whether such rights are or may be taken can be properly analyzed.³⁰ *See Chancellor Manor v. United States*, 331 F.3d 891, 901-02 (Fed. Cir. 2003) (The analysis of whether property rights exist logically must precede an analysis into whether such rights have been taken, and thus trigger constitutionally compelled remedies.).

Finally, the PTO speciously argues that GSK has no viable reasonable-investment-backed expectations because a PTO regulation that predates the Final Rules "already prohibited filings that intentionally delay prosecution." (PTO SJ Br. 49 (citing 37 C.F.R. § 10.18).) But that regulation is simply irrelevant to this inquiry. It is undisputed that under the current patent system there is *no limit* to the number of continuing applications that may be filed absent prosecution laches, a doctrine to be applied "sparingly" and "only in egregious cases." *Symbol IV*, 422 F.3d at 1385-86. GSK has made significant investments and has disclosed protectable

³⁰ The PTO's argument that there are provisions in the Final Rules that moderate or mitigate their deleterious impact (PTO SJ Br. 48-49), is belied by the PTO's own admissions that it crafted the Final Rules to "stop" continuing applications and to limit claims to reduce the backlog of pending applications (*see* TRO Hr'g Tr. 51:5-22).

trade secrets to the public in its patent applications with the reasonable expectation that it will be afforded the full spectrum of protections afforded by the patent system. The Final Rules threaten to destroy those reasonable expectations. (GSK SJ Br. 7-12.)

H. Final Rule 75's Limits On The Number Of Total And Independent Claims Is Not A Logical Outgrowth Of The PTO's Proposed Rule 75.

The PTO asserts that Final Rule 75, which limits an applicant to twenty-five total claims and five independent claims, is a logical outgrowth of its proposed rule, which allowed an applicant an unlimited number of total claims and twice as many independent claims.³¹ However, “a final rule is a ‘logical outgrowth’ of a proposed rule only if interested parties ‘should have anticipated’ that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period.” *Int’l Union, United Mine Workers v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (citation and internal quotation marks omitted); *see also Env’tl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (“The ‘logical outgrowth’ doctrine does not . . . apply where interested parties would have had to ‘divine [the agency’s] unspoken thoughts’ . . . because the final rule was ‘surprisingly distant’ from the Agency’s proposal.” (citations omitted)). Here, interested parties, such as GSK, could not have foreseen the PTO’s drastic shift from proposed to Final Rule 75.

The PTO asserts that Final Rule 75 was “reasonably foreseeable” because, in its claims-related Notice of Proposed Rulemaking (“NPRM 2”), the PTO alluded to a 1998 proposed rule that would have limited the total number of claims. (PTO SJ Br. 61 (citing *Changes to Implement the Patent Business Goals*, 63 Fed. Reg. 53,498, 53,506-08 (Oct. 5, 1998)).) The

³¹ The PTO also asserts, albeit inconsistently, that because the Final Rules are procedural, they were not subject to the notice and comment requirement of APA section 553. (*See, e.g.*, PTO SJ Br. 17-20.) As discussed in sections II.B., II.C., and II.D., *supra*, however, the Final Rules, including Final Rule 75, substantively alter an applicant’s statutory rights. Thus, Final Rule 75 must be vacated if it is not a logical outgrowth of the proposed rule.

PTO's assertion is unsupported by the facts. First, the PTO abandoned the 1998 proposed rule due to the "strong opposition to placing limits on the number of claims in an application." Changes to Implement the Patent Business Goals, 64 Fed. Reg. 53,772, 53,774-75 (Oct. 4, 1999) (stating that the reasons given for opposition to the proposed change included that applicants, not the PTO, "should be permitted to decide how many claims are necessary to adequately protect the invention" and "the proposed change exceeds the Commissioner's rule making authority"). Second, in NPRM 2, the PTO distinguished the strongly opposed 1998 proposal and expressly indicated that it was not considering a limit on the total number of claims:

The Office is now proposing changes to its practice for examination of claims in patent applications that avoids placing limits on the number of total or independent claims that may be presented for examination in an application, but does share with an applicant who presents more than a sufficiently limited number of claims for simultaneous examination the burden so imposed.

(Ex. 7 at 62.)³² Given the fierce opposition to the 1998 proposal, the PTO's withdrawal of that proposal in response to those negative comments, the PTO's attempt to distinguish its 1998 proposal, and the PTO's expressed intent to allow applicants to file an unlimited number of total claims, interested parties could not have anticipated that the PTO would reverse course and cap the total number of claims. Thus, the PTO's "surprise switcheroo" must be rejected, and Rule 75 must be vacated. See *Env'tl. Integrity Project*, 425 F.3d at 996, 998 (vacating final rule and warning that "[i]f the APA's notice requirements mean anything, they require that a reasonable

³² The PTO's 1998 proposal is further irrelevant because, while the 1998 proposed rule would have limited an applicant to six independent and forty total claims, the PTO emphasized that "an applicant would effectively be permitted to present any number of claims for examination by filing any number of continuing applications, each application presenting no more than forty total or six independent claims for examination." 63 Fed. Reg. at 53,508. Thus, the 1998 proposed rule differed significantly from Final Rules 75 and 78, which limit applicants to two continuing applications and each application to no more than twenty-five total or five independent claims, without having to file a petition and showing or an onerous ESD.

commenter must be able to trust an agency's representations about *which particular* aspects of its proposal are open for consideration") (emphasis in original).³³

The PTO also asserts that the new construct of Final Rule 75 is a logical outgrowth of the proposed rule because the "actual comments" received in response to the proposed rulemaking show that the Final Rules were "reasonably foreseeable." (PTO SJ Br. 62.) The PTO cites only two comments—an email comment from an attorney (A01835) and an excerpt from the comments of *amicus curiae* American Intellectual Property Law Association ("AIPLA")—out of the hundreds of pages of overwhelmingly negative comments to NPRM 2.³⁴ However, the fact that "[t]here were some comments" during the comment period does not rescue Final Rule 75 from the logical outgrowth doctrine because NPRM 2 "did not afford . . . public notice of [the PTO's] intent to adopt, much less an opportunity to comment on, such a cap" on the number of

³³ The cases that the PTO cites do not support its course reversal. *See Am. Coke & Coal Chems. Inst. v. EPA*, 452 F.3d 930, 939 (D.C. Cir. 2006) (finding no violation of the logical outgrowth doctrine when the agency made clear in a document that accompanied the proposed rule that the agency might reconsider the derivation of its naphthalene limitation in the proposed rule and include other sampling data); *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1298-1300 (D.C. Cir. 2000) (finding no violation of logical outgrowth doctrine where final rule exempted Indian Tribes from certain judicial review requirements in view of many comments urging such leniency); *Omnipoint Corp. v. FCC*, 78 F.3d 620, 632 (D.C. Cir. 1996) (finding no violation of logical outgrowth doctrine because the FCC adopted rule in view of many comments proposing such rule, the rule was actually "more consistent" with FCC's "desire to avoid disrupting the existing plans . . . ," and "public interest in expedition and finality" outweighed advantages of additional comment).

³⁴ The PTO's reliance on the AIPLA's comments is misplaced. The AIPLA did not propose or support limiting the number of total or independent claims, a proposal it found to be "very troubling." (Ex. 27 at A00670.) Rather, the AIPLA proposed an alternative to limiting the number of claims: that the PTO implement a new fee structure to discourage what the PTO perceived to be "excessive claiming" by imposing a high per-claim cost beyond six independent claims and 30 total claims. (*Id.* at A00672-73.) Significantly, the AIPLA cited *In re Wakefield*, 422 F.2d 897 (C.C.P.A. 1970) for the proposition that "an applicant should be allowed to determine the necessary number and scope of claims." (*Id.* at A00672.) Further, as the AIPLA's two *amicus* briefs demonstrate, it opposes the PTO's limit on the total number of claims. (AIPLA TRO Br. 7-9; AIPLA SJ Br. 4-6, 8-10.)

claims. *Int'l Union*, 407 F.3d at 1261 (Although some comments urged a maximum velocity cap, the court vacated a final rule capping maximum velocity because it was not a logical outgrowth of the proposed rule requiring a minimum velocity.); *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1101, 1103 (4th Cir. 1985) (Although 78 comments recommended that flavored milk be excluded from the food program, the court vacated the final rule because it “dramatically altered the proposed rule,” which included flavored milk.). Thus, the two cherry-picked comments that the PTO relies upon do not justify its assertion that interested parties could have anticipated the caps imposed in Final Rule 75.

Moreover, the drastic difference in the number of applications that the proposed rule and the final rule would affect further evidences that the PTO’s regulatory flip-flop was not reasonably foreseeable. In its proposed rule, the PTO indicated that the representative claims proposal would affect only 1.2% of all applications. (Manbeck Decl. ¶ 60; Ex. 6 at 66.) In sharp contrast, Final Rule 75’s claim limitation would affect 23.7% of applications filed in fiscal year 2006. (Manbeck Decl. ¶ 60; Ex. 1 at 46,788.) The degree of change that Final Rule 75 imposes—an increase of more than 1800% in affected applications—is highly probative evidence of the impropriety of the PTO’s change. (Manbeck Decl. ¶ 60.) Despite the PTO’s attempt to justify Rule 75 as following “the same general approach” as proposed Rule 75 (PTO SJ Br. 61), the facts demonstrate Final Rule 75 is “surprisingly distant” from the proposal and must be vacated. *See Int'l Union*, 407 F.3d at 1260.

I. The Final Rules Are Arbitrary And Capricious In Numerous Respects.

In its motion, the PTO asserts that it designed the Final Rules to eliminate patenting strategies it disfavors—those it terms abusive. (*See* PTO SJ Br. 35.)³⁵ As GSK has

³⁵ GSK has demonstrated that the PTO acted arbitrarily and capriciously in promulgating the Final Rules. (GSK SJ Br. 41-45.) The Final Rules are also independently arbitrary and

demonstrated, however, many of the strategies it and others employ are not abusive and, in fact, have been expressly validated by the Federal Circuit. *See supra* § II.B.-II.D. For example, GSK often files a patent application disclosing a broad genus and many species with the expectation that it can use continuing applications as it learns more about the invention during its continued research into the efficacy of the invention and as it proceeds through the FDA process. The Final Rules would destroy many of the inventions that GSK has already disclosed in pending applications and would drastically reduce the incentive to continue innovating. (*See Knowles Decl.* ¶¶ 8-19; GSK SJ Br. 9-12, 35-36; Am. Compl. ¶¶ 57-58, 147-50.)

Notably, the PTO has not considered the *benefits* of those patenting strategies—not in its brief and not at any point since it proposed the rules. Nothing that the PTO expressly relies on demonstrates otherwise. (*See* PTO SJ Br. 39 (citing Ex. 1 at 46,717, 46,757, 46,7966 [sic], 46,825-26).) Courts readily vacate rules where agencies have failed to *sufficiently* calculate costs or benefits where such an analysis is necessary to strike the proper regulatory balance, never mind where agencies have failed to consider the benefits whatsoever. *See Ctr. for Biological Diversity v. NHTSA*, 508 F.3d 508, 535 (9th Cir. 2007) (“NHTSA’s decision not to monetize the benefit of carbon emissions reduction was arbitrary and capricious, and we remand to NHTSA for it to include a monetized value for this benefit in its analysis of the proper CAFE [corporate average fuel economy regulation] standards.”); *see also Morall v. DEA*, 412 F.3d 165, 167 (D.C. Cir. 2005) (“The agency decision is, in short, stunningly one-sided in its focus and, thus, utterly arbitrary and capricious.”). The PTO responds that it has adequately explained its administrative efficiency and backlog rationales because it need only show that there is a

capricious because the PTO exceeded its authority in promulgating the rules, the rules contradict the relevant sections of the Patent Act, and the PTO failed to appropriately consider its taking of constitutionally protected property rights. *See supra* §§ II.A.-II.D, II.G.

“rational connection between the facts found and the choice made.” (See PTO SJ Br. 36 (citing *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 105-06 (1983).) But the PTO’s failure to consider the benefits of the current regime and the effects of changing the regime is, itself, arbitrary and capricious. See *State Farm*, 463 U.S. at 43 (“Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem . . .”).

Further, although it concedes that only 2.7 percent of applications would be affected, the PTO asserts that its limit on continuing applications is a rational response to its present backlog problem. (PTO SJ Br. 37.) The PTO relies on models, but those models are rudimentary, internally inconsistent, and insufficiently explained. (See GSK SJ Br. 44-45.)³⁶ The PTO’s reliance on such insufficient models requires that the Final Rules be remanded for further investigation. See *Owner-Operator Indep. Drivers Ass’n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 199 (D.C. Cir. 2007) (“Although we apply a deferential standard of review to an agency’s use of a statistical model, we cannot uphold a rule based on such a model when an important aspect of its methodology was wholly unexplained.”); *Sierra Club v. EPA*, 167 F.3d 658, 663-64 (D.C. Cir. 1999) (pronouncing agency’s explanation of its modeling to be arbitrary and capricious and remanding for further explanation).

³⁶ The model that the PTO relies upon (Ex. 26 at A05641-05721) demonstrates that the PTO simplistically assumed that reductions in the number of patents filed or the number of claims-per-application would cause proportionate reductions in examiner workload. This crude analysis demonstrates that the PTO is, in fact, imposing a hard limit despite its arguments to the contrary. (See GSK SJ Br. 44-45.) If, however, the PTO were to use a low threshold in evaluating petitions to exceed the limits, then the model fails to account for the dynamic effects that allowing more continuing applications would have on the purported efficiency gains. (*Id.*) This failure to consider the impact on the purported efficiency gains render the Final Rules arbitrary and capricious. See, e.g., *ASG Indus., Inc. v. CPSC*, 593 F.2d 1323, 1335 (D.C. Cir. 1979) (adopting a regulatory system that fails to provide a reasonable and meaningful basis for projections is arbitrary and capricious).

The PTO also criticizes GSK as contradicting itself by simultaneously arguing that the Final Rules both do too much and too little. (*See* PTO SJ Br. 38.) That is simply incorrect. GSK has demonstrated that the PTO did *too little* in considering the benefits of the regulatory regime and the impact that the Final Rules will have on those benefits. While doing too little analysis, the PTO embarks on a sweeping regulatory shift that goes *too far* in limiting continuing applications, RCEs, and claims with a devastating effect on property rights and incentives to innovate. The PTO's failure to appreciate the enormity of its regulatory action, as evidenced by its misunderstanding of this "too little-too far" problem, demonstrates that the Final Rules are arbitrary and capricious.

III. CONCLUSION

For the foregoing reasons, GSK respectfully submits that the PTO's motion for summary judgment must be denied; instead, GSK is entitled to judgment as a matter of law on each of the counts in its amended complaint. Accordingly, GSK respectfully requests that the Court enter judgment that the Final Rules are invalid, vacate the Final Rules, and grant a permanent injunction against their enforcement.

Date: January 22, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 22, 2008, I electronically filed the foregoing, with attachments, with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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