United States Court of Appeals

for the **Federal Circuit**

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline), SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

ν.

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

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

BRIEF AMICI CURIAE OF INTELLECTUAL PROPERTY AND ADMINISTRATIVE LAW PROFESSORS IN SUPPORT OF APPELLANTS

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JULY 29, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Tafas	v. Dudas
N	O. 2008-1352
CERTIFICA	ATE OF INTEREST
	pondent) (appellee (amicus) name of party) ollowing (use "None" if applicable; use extra sheets
1. The full name of every party or ami	cus represented by me is:
Attached in Appendix A	
2. The name of the real party in interest party in interest) represented by me is:	st (if the party named in the caption is not the real
None	
3. All parent corporations and any pub of the stock of the party or amicus curiae re None	olicly held companies that own 10 percent or more epresented by me are:
	partners or associates that appeared for the party al court or agency or are expected to appear in this
Mark A. Lemley & Jennifer Martinez, Stanford Law S Arti K. Rai, Duke Law School	School
7/28/08 Date	Signature of counsel Mark A Lemlen Printed name of counsel
Please Note: All questions must be answered cc:	d

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Professor John R. Thomas Georgetown University Law Center

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INTEREST OF AMICI

Amici are professors who teach intellectual property, administrative law, or both at law schools throughout the United States. A complete list of signatories is attached as Appendix A. Amici have no personal connection to the parties and no economic interest in the outcome of these cases. We have an academic interest in seeing that patent law develops in ways that promote the progress of the useful arts, and in ensuring that the role of the United States Patent and Trademark Office (PTO) as an administrative agency is properly understood.

ARGUMENT

- I. Evaluation of the Rules is Governed by Step 2 of Chevron
 - A. In *Dickinson v. Zurko*, the Supreme Court Established that Administrative Law Standards Like *Chevron* Apply to the PTO

The Supreme Court's 1999 decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999), enunciated a significant change in judicial review of the PTO. Prior to that time, this Court and its predecessor court, the Court of Customs and Patent Appeals, had often held that the Administrative Procedure Act ("APA"), and associated principles of administrative law, did not apply to their review of the PTO. *See, e.g., In re Zurko*, 142 F.3d 1447, 1450-52 (Fed. Cir. 1998) (holding that review of PTO fact-finding is governed by the

less deferential "clearly erroneous" standard rather than the more deferential APA standard); *In re Portola Packaging*, 110 F.3d 786, 788 (Fed. Cir. 1997) (stating, without analysis, that it would review a patent rejection claim "without deference to the Commissioner's interpretation"); *In re Henriksen*, 399 F.2d 253 (C.C.P.A.1968) (reviewing, without any mention of administrative law principles, the PTO's decision to allow the claiming of an earlier filing date for only two continuation applications). In reversing this Court, the Supreme Court in *Zurko* established that standard administrative law principles govern judicial review of the PTO. *See* Stuart Minor Benjamin and Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn From Administrative Law*, 95 GEO.L.J. 269, 270-71 (2007).

Consistent with *Zurko*, not only does this Court now apply APA language in reviewing PTO fact-finding, but it also applies administrative standards in its review of the PTO's legal determinations. *See*, *e.g.*, *Lacavera v. Dudas*, 441 F.3d 1380, 1383 (Fed. Cir. 2006) (applying deference standard enunciated in *Chevron*, *U.S.A.*, *Inc. v. NRDC*, 467 U.S. 837 (1984) to PTO rulemaking); *Eli Lilly & Co. v. Board of Agents of the University of Wash.*, 334 F.3d 1264, 1266 (Fed. Cir. 2003) (applying deference standard enunciated in *Bowles v. Seminole Rock & Sand Co.*, 325

U.S. 410, 414 (1945), to agency interpretation of its own regulations); *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377 (Fed. Cir. 2002) (applying administrative deference standard enunciated in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1940)).

B. The Rules in Question Are Entitled to Evaluation Under Chevron

In this case, the PTO argues that its action falls within its statutory grant of rulemaking authority and is therefore properly evaluated under the voluminous administrative law that the Supreme Court has developed in *Chevron* and its progeny. Thus, this Court should first decide whether *Chevron* is applicable. *See, e.g., United States v. Mead*, 533 U.S. 218 (2001) (deciding this threshold question when the agency in question was arguing for *Chevron* deference); *see also* Thomas Merrill, *Rethinking Article I, From Nondelegation to Exclusive Delegation*, 104 Colum. L. Rev. 2097, 2171-72 (2004) ("It is difficult to overstate the importance of [*Chevron*] jurisprudence to modern administrative law. The *Chevron* doctrine, as clarified by *Mead*, is the template through which federal courts approach virtually all questions of statutory interpretation when reviewing agency

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¹ We address only how this Court should evaluate the application of the rules to future patent applications. We take no position on plaintiffs' argument that applying the rules to pending patent applications constitutes agency action that is retroactive and hence impermissible.

action. The doctrine has been applied in thousands of cases and serves as the metric by which the relative power of courts and agencies is sorted out at the retail level in the modern administrative state.")

The analysis under *Chevron* – where the court upholds an agency's reasonable interpretation of a statute so long as Congress has not "directly spoken to the precise question at issue," *Chevron*, 467 U.S. at 842-843 – involves substantially more deference than other possible alternatives, such as *Skidmore*-based deference.² Thus the first logical question in evaluating the regulations is whether *Chevron* is applicable.

Under *United States v. Mead*, *Chevron* applies in situations where Congress contemplates administrative action "with the effect of law." *Mead*, 533 U.S. at 230. Congress contemplates such action when it "provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *Id.* at 230. The *Mead* Court specifically notes that a procedure such as notice and comment rulemaking meets its requirements for formality. *Id.* at 230-31.

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² Under *Skidmore*, an agency's argument that its interpretation is consistent with the statute it administers is evaluated on a much looser "sliding scale" – according to the "thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, all those factors which give it power to persuade, if lacking power to control." 353 U.S. at 140; *see also Mead*, 533 U.S. at 228 (quoting this language).

In this case, the Patent Act gives the PTO authority to make regulations governing its internal proceedings and also specifies that these regulations may be made through notice and comment rulemaking. *See* 35 U.S.C. § 2(b)(2)(A)(B) (stating that the PTO "may establish regulations" to "govern the conduct of . . . [its] proceedings" and that these regulations shall be made in accordance with Section 553 of the APA, which provides for notice and comment rulemaking). The PTO has acted using notice and comment rulemaking here.³ Thus, to the extent that the rules in question here are in fact procedural, the *Chevron* framework clearly applies.

The district court opinion below held that the rules in question are substantive, and that the PTO does not have the authority to promulgate substantive rules. In contrast, the PTO argues that the rules fall under the aegis of its statutory authority to "govern the conduct of . . . [its] proceedings." The PTO further argues that its position regarding the scope of its power to make rules with the force of law itself deserves deference.

The relevant Supreme Court decisions do not reach a definitive conclusion on whether agencies' positions regarding the scope of their

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³ As the Appellants' brief correctly notes, the PTO is not required to use such rulemaking. Section 553 of the APA states that notice and comment rulemaking is not required in a variety of cases, including situations where an agency issues "rules of agency organization, procedure or practice." 5 U.S.C. § 553 (b)(3)(A). However, *Mead* makes it clear that the use of notice and comment rulemaking enhances an agency's claim to *Chevron* deference.

rulemaking authority itself deserve deference. But even without the added force of deference, the PTO position is the correct one. The rules at issue are unquestionably directed at the control of PTO procedures – under what circumstances applicants can file continuation applications, and what information applicants must disclose along with those applications that are particularly large. Although the line between procedure and substance is not always clear, the mere fact that procedure can have a substantive impact does not convert procedure to substance. Were it otherwise, no rules would be treated as procedural, because even the most procedural rules can affect substantive outcomes.⁴ In fact, the district court opinion itself acknowledges this reality when it notes (citing *In re Van Ornum*, 686 F.2d 937, 945 (C.C.P.A. 1982)) that "procedural rules with collateral substantive consequences are permissible under Section 2(b)(2)." Slip op. at 17. See

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⁴ For example, the rules that require the application be presented in English (37 C.F.R. § 1.52(b)(1)(ii)) have a substantive impact on outcomes, not only in the sense that applications filed in a foreign language will be rejected, but because the act of translation of the specification and claims may affect the scope and validity of the patent itself. But this substantive impact does not mean that the rules aren't at base procedural, or that the PTO lacks authority to promulgate them. *Cf. Hanna v. Plumer*, 380 U.S. 460, 468 (1965) ("The difference between the conclusion that the Massachusetts rule is applicable, and the conclusion that it is not, is of course at this point 'outcomedeterminative' in the sense that if we hold the state rule to apply, respondent prevails, whereas if we hold that Rule 4(d)(1) governs, the litigation will continue. But in this sense every procedural variation is 'outcome-determinative.'")

also Chamber of Commerce v. Department of Labor, 174 F.3d 206, 211 (D.C. Cir. 1999) (noting that "even a purely procedural rule can affect the substantive outcome of an agency proceeding").

Where the district court errs is in its statement that the rules in question must be substantive because they "constitute a drastic departure from the terms of the Patent Act as they are presently understood." *Id.* at 18. Even assuming that "drastic departure" is the relevant standard,⁵ the opinion wrongly assumes that the rules in fact represent a drastic departure. They do not. With this Court's approval, the PTO already uses the doctrine of prosecution laches to limit continuation applications. *In re Bogese*, 303 F.3d 1362, 1368 (2002). As for the argument that limits on requests for continued

⁵ Notably, the D.C. Circuit – the court that most frequently has occasion to consider the distinction between substantive and procedural rules promulgated by agencies – has moved away from an approach which focuses solely on how large an impact the rule has. See American Hospital Ass'n v. Bowen, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (stating that, when it inquires into whether a rule is procedural, the court has "shifted focus" from a "substantial impact" analysis to one which "inquir[es] more broadly [into] whether the agency action also encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior.") Moreover, the D.C. Circuit has viewed time limits of various sorts as procedural, even when they might be seen as encoding a "substantive value judgment." Specifically, it has held that although rules which promote "efficient application processing" may encode a substantive value judgment about which applications are worth sacrificing for purposes of efficiency, such a judgment does not "convert a procedural rule into a substantive one." National Whistleblower Center v. NRC, 208 F.3d 256, 262-63 (D.C. Cir. 2000) (citing cases).

examination (RCEs) represent a "drastic departure," the district court itself acknowledges that because RCEs are a recent innovation, there is simply no law interpreting the language of the relevant statutory section. Slip op. at 20.

Most importantly, this court has already held that steps taken to control continuation applications are in fact procedural in nature. *Bogese* at 1368 (upholding PTO decision to reject patent application that had been the subject of multiple continuations on the grounds that the agency "has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications.")

It seems even more obvious that the so-called "5/25" rules requiring the submission of certain information govern procedures for prosecuting applications in the PTO. The district court opinion holds that because these rules require applicants who submit large applications to perform prior art searches, they "manifestly change[] existing law" and are therefore substantive. Slip op. at 25. The district court's statement regarding "manifest change" is (to put it charitably) highly overstated. This court has already approved the PTO's use of its procedural rulemaking authority to promulgate Rule 105, which authorizes examiners to require additional

information from applicants not simply in cases of large applications but in *all* cases. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2005). In fact, according to this court, the applicant must turn over information under Rule 105 even when the applicant does not itself deem the information material to patentability. *Id.* at 1282. It is odd indeed to conclude – as the district court implicitly did – that the broader power of Rule 105 is procedural, but that the more tailored application of the 5/25 rules is somehow substantive.

Because the PTO followed the statutorily prescribed notice-and-comment rulemaking mechanism, and because the rules are within the scope of its statutory authority to regulate procedure, the *Chevron* framework should apply.⁶

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⁶ It bears noting that, even if the framework of *Chevron* and *Mead* did not apply (because, for example, Congress had not given the PTO notice-and-comment rulemaking authority in this area), Supreme Court case law holds that agencies have considerable discretion in formulating procedures. As the Court observed in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978), "administrative agencies and administrators will be familiar with the industries they regulate and will be in a better position than federal courts or Congress itself to design procedural rules adapted to the peculiarities of the industry and the task of the agency involved." *Id.* at 525 (citing *FCC v. Schreiber*, 381 U.S. 279, 290 (1965)).

C. Because Congress Has Not "Directly Spoken to the Precise Question at Issue," the PTO's Rules Must be Accepted So Long As They Are Reasonable

For appellees' challenge to succeed under the first step of *Chevron*, the relevant statutory language must *require* the PTO to: 1) entertain an unlimited number of continuation applications and 2) place no additional requirements on particularly large applications. However, under a fair reading of the relevant sections of the patent statute, it cannot be said that Congress has spoken directly to these questions.

1. The Statute Does Not Prevent the PTO from Limiting Continuation Applications

The use of continuation applications is governed by 35 U.S.C. § 120, which provides that a continuation application that meets certain specified criteria "shall have the same effect . . . as though filed on the date of the prior application" to which it makes reference. The point of this statutory provision is to allow applicants that file continuation applications to benefit from the priority date of the first application. Without that benefit, the original application would often serve as prior art that would bar the continuation application.

Section 120 does not compel the PTO to give applicants an unlimited numbers of bites at the apple. Far from it. Section 120 provides only that

continuation applications are entitled to the priority date afforded the original application from which they descend. But to issue as patents, those continuation applications must also meet all the requirements of patentability – including those regulations promulgated by the PTO under its procedural rulemaking authority.

In *Bogese*, the PTO refused to continue examining Bogese's applications after he filed multiple continuations in which he continued to argue he was entitled to his original claims. There, as here, Bogese argued that the PTO lacked "statutory, regulatory, or case law support" to impose any limit on his ability to file continuation applications. The Federal Circuit disagreed. It concluded that the PTO had the authority to reject applications after "unreasonable and unexplained delay in prosecution," just as the courts did under the doctrine of prosecution laches. *Bogese*, 303 F.3d at 1367.

Appellees contend that *Bogese* authorizes only case-by-case rejections of applications that abuse the continuation process. But that argument makes little sense as a matter of administrative law. Case-by-case rejections by the PTO occur in *ex parte* informal adjudications. *Mead*'s emphasis on formality means that an administrative agency that acts under the auspices of its notice-and-comment rulemaking authority when making procedural decisions has *more* power, not less, than when it uses informal adjudication.

More generally, the strength of an administrative agency compared to a court is precisely in the gathering of evidence and the setting of generally applicable rules, something the PTO did with care here. It would be perverse to conclude that the PTO has the power to individually reject each one of the appellees' pending applications because they have filed too many continuation applications – something *Bogese* makes it clear they can do – but no power to set general rules that provide guidance and certainty to applicants.

In any event, the Federal Circuit rejected plaintiffs' argument that *Bogese* was limited to the application of equity on a case-by-case basis in the decision itself, holding that "the PTO's authority to sanction undue delay is even broader than the authority of a district court to hold a patent unenforceable." *Id.* at 1367. Indeed, it proceeded to consider at length whether 37 C.F.R. §1.111 justified the PTO's rejection of *Bogese*'s application, a discussion that would have been entirely irrelevant if the PTO had no power at all to promulgate general regulations that controlled abuse of continuation applications as opposed to making case-by-case determinations.

Nor does *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968), establish an explicit statutory limit on the power of the PTO to regulate continuations. In

that case, the PTO interpreted section 120 as *requiring* it to deny priority status to any application after the second continuation, on the theory that the statute only made reference to continuations that specifically refer to the original application or "an application similarly entitled to the benefit of the filing date of the first application." 35 U.S.C. § 120. The PTO argued that the statute by its terms could only apply to continuations based on the original or on the first continuation. The Court of Customs and Patent Appeals rejected that reading of the statute, concluding that any number of continuations in a chain could be entitled to the priority date of the original application if they met the requirements of the statute. *Henriksen*, 399 F.2d at 261.

But the court's holding was limited to the question of entitlement to the priority date. Indeed, it quoted with approval P.J. Federico, one of the drafters of the 1952 Patent Act, who said "Section 120 codifies the present practice *relative to the right to the filing date of an earlier application* for common subject matter in a continuation application." *Id.* at 258 (emphasis added). *Henriksen* resolved only the question of whether section 120 precluded the PTO from giving applications in a continuation chain priority. It did not hold that section 120 precludes the PTO from imposing requirements governing the prosecution of patents. *See* In re *Bogese*, 303

F.3d 1362, 1368 n.6 (Fed. Cir. 2002) ("Nowhere does *Henriksen* suggest or imply that the PTO must allow dilatory tactics in the prosecution of applications or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution."). And nothing in the language of section 120 purports to do so.

Even if *Henriksen* were read more broadly, as interpreting Section 120 to prohibit any limit on *numbers* of continuation applications, the decision makes no claim that Section 120 is "unambiguous" on the question. To the contrary, as discussed below, the court delved deeply into legislative history and prior practice to find even slender evidence against the PTO's view. This is important because the Supreme Court has recently made it clear that unless a judicial interpretation of a statute follows from its "unambiguous terms," such an interpretation does not foreclose *Chevron* deference to a future agency construction. National Cable & Telecommucations Assn. v. Brand X Internet Services, 545 U.S. 967, 982 (2005) (emphasis added) (stating that "[a] court's prior judicial construction of a statute trumps an agency construction otherwise entitled to Chevron deference only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for *agency discretion.*")

In *Henriksen*, the court said that the "express terms" of Section 120 did not "unequivocally prohibit" obtaining the benefit of an earlier filing date through a third continuation application. 399 F.2d at 256. Significantly, the court did *not* say that the statutory language "unequivocally prohibited" the agency from adopting an interpretation that limits numbers of continuations. Thus, even if *Henriksen* is seen as a case about limiting continuations rather than simply about priority dates, nothing in *Henriksen* interprets the statutory language as compelling the PTO to accept an unlimited number of applications.

Instead of relying on statutory language, the *Henriksen* opinion turns to the legislative history of Section 120, which was enacted by Congress as part of the 1952 Patent Act. In recounting this legislative history, the court admits at the outset that it is "somewhat inconclusive." *Id.* at 256. Faced with this murky situation, the court emphasizes statements in a House Committee report noting that Section 120 expresses "certain matter which exists in the law today but which had not before been written into that statute . . ." *Id.* at 258 (citing H.R. Rep. No. 1923, 82d Cong., 2d Sess. (1952)). The *Henriksen* court investigates the pre-1952 practice and finds one case involving more than two continuation applications. *Id.* at 259 (citing decision in *Ex Parte Harris*, 55 USPQ 329 (Pat.Off.Bd.App. 1942)). It also

fails to find any case explicitly stating a limit on numbers of continuation applications. *Id.* at 260. On the basis of this relatively slender evidence, the court rejects the PTO's argument that the statute compels its reading.

Thus, even if *Henriksen* is seen as expressing a broad finding about numbers of continuation applications, this finding is hardly a consequence of "unambiguous" language. In such a case, the *Brand X* Court's declaration that agencies cannot, and should not, be precluded from "revising unwise judicial constructions of ambiguous statutes," *Brand X*, 545 U.S. at 983, is entirely apt. *Henriksen*, decided before the Supreme Court held that standard administrative law applies to the PTO, does not preclude the PTO from interpreting the statute differently under the auspices of its administrative authority.

2. The Statute Does Not Prevent the PTO from Requiring Additional Information on Large Applications

Contrary to plaintiff's argument, there is no language in Sections 111 or 112 of the Patent Act that prevents the PTO from requiring additional information on large applications. In fact, as noted earlier, this court has already approved the PTO's use of its procedural rulemaking authority to require patent applicants to submit information. In *Star Fruits S.N.C. v. United States*, 393 F.3d 1277 (Fed. Cir. 2005), this court explicitly approved

the PTO's promulgation of Rule 105, which allows an examiner to require the submission of "such information as may be reasonably necessary to properly examine or treat the matter." 37 C.F.R. §1.105(a)(1). The *Star Fruits* court emphasized that "through notice and comment rulemaking the Office made explicit the inherent authority of Office employees to require information from an applicant." 393 F.3d at 1282.

Just as the PTO has the power to compel applicants to disclose information in particular cases, it also has the power to define a class of cases in which applicants must submit particular types of information. That is precisely what it has done in the 5/25 regulation. Nothing in the statute purports to limit the PTO's ability to compel information, and *Star Fruits* makes it clear the PTO has – and indeed in other circumstances already exercises – that power.

II. The PTO Rules Are a Reasonable Interpretation of the Statute

The PTO rules clearly meet the extremely deferential "reasonableness" standard enunciated in *Chevron* step 2. Agency interpretations of statute that are found to be unclear under *Chevron* step 1 are almost always found to be reasonable. In fact, in the more than twenty years since the *Chevron* test has been in force, only two Supreme Court cases have held that administrative interpretation of a statute was

unreasonable under *Chevron* step 2. *See Whitman v. Am. Trucking Ass'ns*, Inc., 531 U.S. 457, 482 (2001); *AT&T Corp. v. Iowa Utils. Bd.*, 525 U.S. 366, 392 (1999).

This case is hardly the rare exception that fails under step 2. It is perfectly reasonable for the PTO to attempt to manage its ever-burgeoning case load by preventing the repeated filing of applications directed at the same subject matter. It is also reasonable for the PTO, which has only a small amount of time to review any given application, to seek additional information on applications with large numbers of claims.

Because *Chevron* applies, and because the rules are not invalid under either step one or step two of *Chevron*, the rules must be upheld unless they are arbitrary and capricious.

III. The PTO's Rules Are Not Arbitrary and Capricious

To pass arbitrary and capricious review, the agency must have examined relevant data and must have articulated a satisfactory explanation for its decision. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983). The PTO's decision in this case satisfies the arbitrary and capricious standard. Even if the PTO's solution to the problem it faces is not necessarily the optimal one, it is satisfactory.

A. The Administrative Record Indicates that the PTO Evaluated the Relevant Data

In this case, the PTO received feedback in town hall meetings and presentations as well as over five hundred written comments. *Changes to* Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716, 46717 (Aug. 21, 2007). It spent more than a year analyzing the comments. *Id.* In response to the comments, it changed its proposal from one that would have automatically allowed only one continuation, continuation-in-part, or request for continued examination to a proposal that automatically allows two continuations or continuationsin-part as well as one request for continued examination. *Id.* at 46718. The rules also permit applicants to seek additional continuations beyond the three allowed automatically on a showing of good cause. Following the recommendation of various commentators, the PTO also changed its original proposal for "representative claims" designation into the current "5/25" rule. Id.

B. The PTO Has Shown Satisfactory Reasons for Limiting the Abuse of Continuation Practice

The United States is alone in the world in making it impossible for the PTO ever to finally reject a patent application. The fact that an applicant can

file an unlimited number of continuation applications creates a number of serious problems, both for the administration of patent prosecution in the PTO and for society at large. At the PTO, multiple continuations add to congestion at the office, slowing the prosecution of other original applications, reducing the amount of time examiners can spend on each application, and necessitating the hiring of more examiners. See id. at 46718. Multiple continuations complicate the evaluation and promotion of examiners, since they make it difficult to measure examiner progress on, and disposal of, applications. They also affect the way examiners approach patent applications. An examiner who knows that the applicant can always come back and ask for more may be unwilling to stand by a rejection she believes to have merit, simply because it is easier in the long run to allow a patent than to continue fighting against a determined applicant. Alternatively, examiners may put off difficult decisions in initial prosecution, relying on the likelihood that patent applicants will file a continuation application (or perhaps even hoping that they will do so, because such applications represent a relative easy opportunity to secure the "counts" on which examiners are evaluated). Either effect can distort the

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⁷ This is particularly true of Requests for Continued Examination (RCEs), because under PTO practice they are taken up out of order, ahead of earlier-filed original patent applications.

process by which examiners are supposed to serve the public interest, sorting legitimate claims from illegitimate ones.

Continuations – particularly multiple continuations – also have a number of detrimental effects on society. First, at a minimum, continuation practice introduces substantial delay⁸ and uncertainty into the lives of a patentee's competitors, who cannot know the claims of a patent application until the last in a series of continuations has issued as a patent. Second, the fact that examiners can never finally reject applications, but can allow them, means that error costs are asymmetric – when the PTO wrongly rejects an application, the applicant will file an RCE or continuation to correct that error, but when the PTO wrongly approves an application, no one will object. Assuming that examiners make mistakes in a certain percentage of cases, the more bites at the apple the applicant has, the more likely those errors are to result in a wrongly issued patent. Third, continuation practice can be—and has been—used strategically to gain advantages over competitors by waiting to see what product the competitor will make, and then drafting patent claims specifically designed to cover that product.

⁸ Based on 1996-1998 data, original applications take on average 1.99 years from their filing to issuance. Applications with at least one continuation, by contrast, take on average 5.23 years. *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Prosecution*, 53 VAND. L.REV. 2099, 2171 tbl. 24 (2000).

Finally, some patentees have used continuation practice to delay the issuance of their patent precisely in order to surprise a mature industry, a process known as "submarine patenting." *See id.* at 46718-46719 (citing Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U.L.Rev. 63 (2004)).

To be sure, there are legitimate reasons applicants might use continuations. The two most plausible are to correct errors – either the examiner's erroneous rejection of an application or the applicant's error in drafting patent claims – and to obtain a narrow patent quickly while fighting over broader claims in a continuation. But it is worth noting that patent law provides a number of other mechanisms for error correction, including a right to appeal rejections to the Board of Patent Appeals and Interferences and then to the Federal Circuit, 35 U.S.C. §§ 134, 141; the right to seek broader claims through filing a reissue application, 35 U.S.C. § 251; and the right to argue for broader protection than the claims provide under the

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⁹ The pharmaceutical industry has argued that it needs multiple continuations in order to file later applications covering particular drugs in a general class once it decides to develop and market those drugs. But if drug companies in fact have described and enabled a group of chemicals of which the drug is a part, they can patent the entire group at the outset without any need for a later continuation application. And if they haven't in fact described and enabled the specific chemical at the time they file their initial application, they are not entitled under 35 U.S.C. § 112 ¶ 1 to later claim that specific chemical and still benefit from the earlier filing date.

doctrine of equivalents, see Graver Tank & Mfg. Co. v. Linde Air Prods., Inc., 339 U.S. 605 (1950).

As noted earlier, the PTO has accommodated these conflicting concerns, in fact bending over backwards in its final rulemaking to ensure that applicants have abundant opportunity to use continuations for these legitimate purposes while still trying to impose some limits on abuse of the continuation process. The final rules permit applicants an original application, two continuation applications, an RCE, and an unlimited number of divisionals. Those who have already exhausted all those applications can seek additional continuations; they simply need to come up with a reason why they need a fifth (or more) bite at the apple. Given the problems with delay, uncertainty, and abuse of the continuation process, and the problems multiple continuations create for PTO administration and examiner evaluation, the PTO's accommodations to the interests of the patent bar are more than generous. The PTO's balancing of legitimate uses of continuations against their procedural and substantive problems cannot be said to be arbitrary and capricious.

C. The PTO Has Shown Satisfactory Reasons to Require the Submission of Information by Applicants Who File Large Patent Applications

Some patent applications are far more complex than others. There is evidence that the applications with more patent claims also tend to have more prior art citations. Because patent examiners operate under extreme time constraints – they can devote no more than 16-18 hours per patent on average, see John R. Thomas, Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties, 2001 U. ILL. L. REV. 305, 314 – they may be unable to review complex patent applications in detail without assistance. Instead, they may give multiple prior art references, or even multiple claims, only passing scrutiny. This is particularly troubling because the applications with the most claims and prior art citations tend to be the most valuable and important once they issue as patents, and the ones most likely to be litigated. See, e.g., John R. Allison et al., Valuable Patents, 92 GEO. L.J. 435 (2004). The 5/25 regulations are an attempt by the PTO to enlist the aid of applicants in focusing the prior art analysis in these complex applications.

It is hard to deny that the PTO is facing a problem, and its approach to that problem does not seem arbitrary or capricious.

IV. Conclusion

Because the PTO rules fall within the agency's procedural authority, and because they were promulgated using statutorily prescribed notice-and-comment rulemaking, they are entitled to evaluation under *Chevron*.

Whether or not the rules represent the best possible solution to the problems the PTO has identified, they are consistent with the statute, reasonable under *Chevron* step 2, and are not arbitrary and capricious.

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CERTIFICATE OF SERVICE

I, EUSSA Mutas, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Mark A. Lemley, Attorney for *Amici Curiae*, to print this document. I am an employee of Counsel Press.

That on the 29th Day of July, 2008, I served the within BRIEF AMICI CURIAE OF INTELLECTUAL PROPERTY AND ADMINISTRATIVE LAW PROFESSORS IN SUPPORT OF APPELLANTS upon:

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