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By Email Nicholas_A._Fraser@omb.eop.gov

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Office of Information and Regulatory Affairs
Office of Management and Budget725 17th St. NW
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Re: Information Collection Request, Comment Request 0651-00xx, 73 Fed. Reg. 58943 (Oct. 8 2008, submitted to OMB Oct. 10, 2008)

Letter 1. Modification of Proposed Rule Language with Massive Paperwork Burden Consequences

Dear Mr. Fraser:

I appreciate the opportunity to comment on the PTO's Information Collection Request (ICR) 0651-00xx. This is the first of several letters I will send you on this ICR.

- In the Final Rule, the PTO "substantially modified" completely reversed a crucial provision of the proposed rule
- This change alone results in uncounted but massive new paperwork burdens because it would require applicants to predict and respond to unstated, possible future examiner positions. If they cannot make these predictions accurately and comprehensively, applicants will lose many cases before the Board of Patent Appeals and Interferences (BPAI) that on the merits they should win.
- Although this change violates the Administrative Procedure Act, OMB is authorized by 44 U.S.C. § 3507(d)(4)(D) to disapprove the ICR based solely on this change and thereby eliminate the need for wasteful and expensive litigation that does not serve the public interest.
- The burden of this change is difficult to estimate, in part because its effects are so widespread. Applicants will have to perform much more intensive work on most of the 400,000 patent applications filed each year – not just the applications

that are actually appealed – because applicants cannot know in advance which applications will need to be appealed and which will not.

• If each application requires just 6 additional hours of attorney time – a realistic average figure – the total additional burden would be about **\$1 billion per year** for only these two provisions of the final rule.

OMB is well within its statutory authority to disapprove ICR 0651-00xx and direct the PTO to fully comply with the law in every respect. Alternatively, OMB could approve only those burdens associated with the appeal regulations that have been in place for years and for which the PTO has never before sought a valid OMB Control Number. This generous compromise would enable the PTO to first reconcile its past illegal conduct, which might have been inadvertent, but refrain from rewarding the PTO for conduct that it knows is illegal and for which it apparently expects OMB to cover up on its behalf.

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I. Introduction

A. Patent Law Requires Examiners to Raise Issues of Unpatentability

The Patent Act obligates the PTO not to issue invalid patents. To fulfill this obligation, examiners <u>must</u> raise issues of unpatentability no matter the stage of proceedings. This applies to appeals filed by applicants to the Board of Patent Appeals and Interferences (BPAI).

Patent examiners will, from time to time, recognize new questions after an appeal has commenced. The 2004-vintage appeal rules recognize this by specifically allowing examiners to raise new issues. There are many reasons this might happen: though some examiners are not diligent during regular examination and only fully engage once an application reaches appeal, even the most diligent examiner occasionally misses an issue that speaks directly to patentability and thus, by law, must be raised.

B. 2004 Regulatory Reforms Provided Applicants Protection from New Grounds for Rejection Raised at Appeal

The 2004-vintage rules provide adequate procedural safeguards so that when a "new ground of rejection" arises, the applicant has straightforward options to pursue, and is not unduly disadvantaged. An applicant has the option of introducing new affidavits to overcome the examiner's new positions and taking the issue to the Board. Alternatively, the applicant can agree with the examiner and drop the issue or drop the appeal in favor of resumed normal examination.

C. The 2007 Proposed Rule Retained These Procedural Safeguards

The 2007 Proposed Rule also recognized examiners' statutory need to be able raise new issues in an appeal. The Proposed Rule weakened these procedural safeguards by barring applicants from filing new affidavits to overcome new factual assertions or new evidence introduced by an examiner, and some public commenters

¹ See, e.g., 2004 version of 37 C.F.R. § 41.37(b).

strongly objected to this change. Otherwise, the Proposed Rule followed the same broad contours.²

D. Without Any Support in the Record, the 2007 Final Rule Took These Safeguards Away

In the 2008 Final Rule the PTO reversed field completely. Final Bd.R. 41.39(b) says examiners are no longer permitted to raise any new issue in appeal. The PTO also eliminated the procedural safeguards that protect applicants' right to contest examiner positions they believe are in error. In theory, these procedural safeguards are not necessary if examiners are prohibited from raising new issues during appeal.

The problem with this neat, "burden-reducing reform" is that it is inconsistent with the Patent Act. Examiners have a statutory <u>obligation</u> to raise questions of patentability at any time they arise. The PTO cannot repeal the Patent Act by rule. Examiners will continue to raise new grounds for rejection, even if the text of the rule says that they cannot, because the law requires them to do so.³

E. The New Rule Denies Applicants a Fair Opportunity to Contest New Grounds for Rejection

The <u>actual</u> effect of new Bd.R. 41.39(b) was known to the PTO, because the 2008 final rule is essentially identical to the rule in effect from 1997 to 2004.⁴ The final 2008 rule creates a seriously uneven contest ensuring that examiners are much more likely to prevail in appeals that applicants should win on the merits. Examiners have

² See, e.g., NPRM Bd.R. 41.37(b)(1), (b)(2), 41.41(h), 41.44(a), 41.44(d)

³ Blacklight Power Inc. v. Rogan, 295 F.3d 1269, 1273-74, 63 USPQ2d 1534, 1537 (Fed. Cir. 2002); Ex parte Peppel, 1998 WL 1766687 at *4, http://des.uspto.gov/Foia/ ReterivePdf?system=BPAI&fINm=fd982848 at page 9 (BPAI 1998) (""While it is unfortunate that the Examiner [raised a new rejection too late,] there is nothing that can be done. Examiners are charged with making sure that an 'applicant is entitled to a patent under law,' 35 U.S.C. § 151. A statutory ground of rejection cannot be dismissed just because it was not entered earlier.")

⁴ RIN 0651-AA80, Changes to Patent Practice and Procedure, 62 Fed. Reg. 53132, 53168 (Oct. 10, 1997) (amending 37 C.F.R. § 1.193(a)(2) to read "An examiner's answer must not include a new ground of rejection").

unconstrained freedom to raise any issue at any time, to introduce new evidence or to change their analyses at any time. However, applicants facing new grounds for rejection can only argue that the examiner is wrong. They <u>cannot</u> introduce new evidence, and they <u>cannot</u> amend the application as they do during normal prosecution. The 2008 Final Rule even takes away applicants' option to discontinue the appeal process and return to regular prosecution before the examiner. When the examiner throws a "late hit," the applicant is <u>absolutely powerless</u> to do anything to defend, counter, or even retreat.

F. The Practical Effect of the New Rule is to Make Applicants Responsible for Examiner Negligence and Misconduct

In the Final Rule preamble, the PTO states both explicitly and implicitly that it will now be the applicant's burden to anticipate every new position an examiner might take during a subsequent appeal and preemptively erect defenses against those positions during regular prosecution. Anything an examiner asserts during an appeal will be presumed correct unless contradicted by evidence placed in the file by the applicant during normal prosecution – that is, prior to the commencement of an appeal.

G. Vast New Paperwork Burdens Arise Because of This Burden-Shift

To maintain the same likelihood of prevailing on appeal, an applicant and his counsel must anticipate every conceivable position the examiner might take at a future date. Each such position must be countered with evidence, often in the form of expert affidavits, submitted to the file. Applicants must undertake this even if the examiner has not raised the issue, because once the appeal process starts, the opportunity for applicants to submit these affidavits is closed. The burden of achieving his new duty of omniscience imposed by the PTO is incalculably large, so the practical result is that many deserving appeals will not be filed.

If the PTO's objective is to radically reduce the number of appeals filed irrespective of the merit of the quality of examination, this is a perfect tactic. However, if

the PTO's objective is (as the Patent Office so often claims) to improve patent quality, this tactic will simply destroy billions of dollars worth of legitimate patent value. Only the very highest valued innovations will be protected by patent.⁵

II. The Final Rule Reverses the Proposed Rule, and the PTO Failed to Follow the § 3507(d)(4) Paperwork Clearance Procedure for This Change

44 U.S.C. § 3507(d)(4)(D) gives OMB the power to disapprove this information collection if the final rule is "substantially modified" from the proposed rule, and the agency did not give the public or OMB an opportunity to comment on the change:

§ 3507(d)(4) No provision in this section shall be construed to prevent the Director, in the Director's discretion--

- (D) from disapproving any collection of information contained in a final rule, if--
- (i) the Director determines that the agency has substantially modified in the final rule the collection of information contained in the proposed rule; and
- (ii) the agency has not given the Director the information required under [§ 3507(d)(1)] with respect to the modified collection of information, at least 60 days before the issuance of the final rule.

Both prongs of this section apply. It is already understood that the PTO provided <u>no</u> opportunity to comment on preliminary burden estimates for any part of the Proposed Rule, and indeed, the Patent Office certified that the Proposed Rule contained no new paperwork burdens at all. The textual change between the Proposed Rule and the Final Rule could not be more "substantially modified," as the side-by-side table below shows.

Final Bd.R. 41.39(b) triggers this provision, as well as several other grounds.

⁵ The Final Rule erects a burden that is overcome by high dollar value, not high quality.

2007 Proposed Rule	2008 Final Rule
(b) New rejection in examiner's answer. An examiner's	§ 41.39(b) No new ground of rejection. An examiner's
answer may include a new rejection. If an examiner's	answer shall not include a new ground of rejection.
answer contains a rejection designated as a new	
rejection, appellant must, within two months from the	
date of the examiner's answer, exercise one of the	
following two options or the application will be deemed	
to be abandoned or the reexamination proceeding will be	
deemed to be terminated.	
(1) Request to reopen prosecution. Request that	{deleted}
prosecution be reopened before the examiner by filing a	
reply under § 1.111 of this title with or without	
amendment or submission of evidence. Any amendment	
or evidence must be responsive to the new rejection	
(2) Request to maintain the appeal. Request that the	{deleted}
appeal be maintained by filing a reply brief as set forth	
in§ 41.41 of this subpart. A reply brief may not be	
accompanied by any amendment or evidence, except an	
amendment canceling one or more claims which are	
subject to the new rejection.	
§ 41.43 Examiner's response to reply brief.	{deleted}
Upon consideration of a reply brief, the examiner may	
withdraw a rejection and reopen prosecution or may	
enter a supplemental examiner's answer responding to the reply brief.	

In the final rule, the PTO turned this scheme around 180°. As amended in the Final Rule Notice, Bd.R. 41.39(b) states "An examiner's answer shall not include a new ground of rejection." This is nonsense on stilts – it ignores both the law and history.

The first violation of the Paperwork Reduction Act by final Bd.R. 41.39(b) is the requirement of § 3506(c)(2)(A)(i), that an information collection must be "for the proper performance of the functions of the agency." On its face, this rule obligates the PTO to break the law by issuing invalid patents. The PTO has long recognized that it has a legal obligation to raise issues of patentability, no matter when they are recognized. It is incompatible with "the functions of the agency" for the PTO to lock itself into granting

⁶ This was illegal under the Administrative Procedure Act. 180° changes between an NPRM and final rule without a new round of notice and comment violate the "logical outgrowth" requirement for APA notice and comment, and such rules are invalid. *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

an invalid patent because an ill-considered rule requires an examiner to ignore issues when they recognize them.⁷

Second, this 180° reversal squarely triggers § 3507(d)(4). The PTO did not submit the revised rule for review.

Third, the PTO previously admitted that the "no new grounds" scheme was unworkable. During 1997-2004, when the same law was in effect, "new grounds of rejection" were nonetheless raised by examiners with some frequency, and the Board often found itself caught between incompatible substantive and procedural law. When the PTO finally admitted in 2004 that this approach was unworkable, the PTO noted that examiners could do a <u>better</u> job, and applicants would have a fair opportunity to respond. This unexplained return to a failed experiment violates § 3506(c)(2)(A)(i), the requirement that information collections promote "the proper performance of the functions of the agency."

Fourth, the 2008 final version of Bd.R. 41.39 confines an applicant to filing a "continuation" application or "request for continued examination" (RCE) in order to present the necessary "amendment, affidavit, or evidence." Under current law, that filing may be made as of right, on payment of a fee and an hour or so of preparing papers for filing. However, under the Continuations Rule that the PTO continues to

⁷ Blacklight Power Inc. v. Rogan, 295 F.3d 1269, 1273-74, 63 USPQ2d 1534, 1537 (Fed. Cir. 2002); Ex parte Peppel, 1998 WL 1766687 at *4, http://des.uspto.gov/Foia/ ReterivePdf?system=BPAI&fINm=fd982848 at page 9 (BPAI 1998) (""While it is unfortunate that the Examiner [raised a new rejection too late,] there is nothing that can be done. Examiners are charged with making sure that an 'applicant is entitled to a patent under law,' 35 U.S.C. § 151. A statutory ground of rejection cannot be dismissed just because it was not entered earlier.")

⁸ E.g., Ex parte Brissette, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd991499 at 3 n.1, 2002 WL 226585 at *1 n.1 (BPAI May 19. 2000)

⁹ RIN 0651–AB32, Rules of Practice Before the Board of Patent Appeals and Interferences, Final rule, 69 Fed. Reg. 49960, 49963 (Aug. 12. 2004).

This alone has a substantial economic effect. Filing of an RCE – rather than pursuing these issues within an appeal, as in the 2004 rules, deprives an applicant of substantial patent term. 35 U.S.C. § 154(b)(1)(B)(i), § 154(b)(1)(C).

pursue,¹¹ an applicant must often file a petition¹² to be permitted to file that continuation or RCE.¹³ The PTO has indicated that it intends to grant these petitions very sparingly, so the burden of preparing this petition will be <u>very</u> substantial. The PTO has not even acknowledged the existence of this burden in this ICR, let alone made any objective attempt to estimate it. Final Bd.R. 41.39 violates the PTO's obligation of objective estimation.

The PTO changed the rule 180° between the NPRM and the final rule, and "has not given the Director the information required under [§ 3507(d)(1)]." The ICR should be disapproved.

III. By Shifting the Burden of Proof, the PTO Adds Incalculable Burdens to Appeals and to Pre-Appeal Prosecution

For decades, the courts have uniformly held that the burden of proof is always on the PTO to establish unpatentability to a preponderance of the evidence. This level of burden of proof applies to both the examiner and the Board.¹⁴ That is, if the evidence is in equipoise, the applicant wins. The evidence is to speak for itself – the examiner's

¹¹ Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, Final Rule, 72 Fed. Reg. 46716 (Aug. 21, 2007), final rule

¹² Aug. 21, 2007 version of 37 C.F.R. § 1.78(d)(1)(vi) or § 1.114(g).

¹³ The PTO stated that "will likely not grant the petition for an additional continuing application or request for continued examination" arising out of "issues pertaining to inadequate examination,"72 Fed.Reg. 46771, col. 2. Not only is the paperwork burden substantial, the PTO's willingness to correct its own errors substantially deprives applicants of important property rights.

In re Swanson, 540 F.3d 1368, 1377, 88 USPQ2d 1196, 1203 (Fed. Cir. 2008 ("In PTO examinations ... the standard of proof [is] a preponderance of evidence"); *In re Kahn*, 441 F3d. 977, 989, 78 USPQ2d 1329, 1338 (Fed. Cir. 2006) ("the Board need only establish motivation to combine by a preponderance of the evidence"); In re Glaug, 283 F.3d 1335, 1338, 62 USPQ2d 1151, 1153 (Fed. Cir. 2002) ("patentability is determined by a preponderance of all the evidence"); *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.")

interpretation of the evidence is entitled to no more (and no less) weight than the applicant's.

It has also been clear for decades that an examiner's view of what the law is, and the application of the law to facts, is reviewed *de novo*, "from new," with no deference, no weight toward either applicant or examiner, on the Board's independent judgment. The Board is to reexamine these issues on a blank slate. Most importantly, the examiner's opinion of "claim construction," the interpretation of what a claim covers, the single most important issue in the vast majority of patent cases, has historically been given no weight – the Board has reviewed this issue *de novo*. This is a practical necessity: only a tiny fraction (under 10%) of all examiners have law degrees.

In this rulemaking, the PTO clearly shifts the burden of proof – while disingenuously stating it is not doing so. The PTO's own explanation states that anything an examiner says – a bald assertion of fact with no evidentiary support, an assertion of what the law is, or a finding of application of law to the facts – will be taken as correct, unless an applicant makes a showing of error:

In most appellate administrative and court tribunals, a decision under review is presumed to be correct until an appellant can convince the appellate tribunal that the decision is incorrect, whether the decision involves a question of fact or an issue of law or both. As one comment correctly stated: "[t]he appellant has to make the case for error on the record." On appeal to the Board, an appellant can overcome a rejection by showing insufficient evidence to support a *prima facie* case or rebutting any *prima facie* case with appropriate evidence.

Giving the benefit of doubt to an examiner until an applicant proves error is the very definition of a shift of the burden of proof. The new "presumptions" in favor of an examiner are similarly and unquestionably shifts of the burden of proof.

This is a giant thumb on the scale, and applicants will work hard to counterbalance it, using similar techniques, and with similar burdens, to those we

¹⁵ Ex parte Toda, 2001 WL 1729659 at *3, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd980078 at 6 (BPAI Apr. 26, 2001)

discuss in § I.G at page 5. The PTO does not even acknowledge the existence of the burdens imposed, let alone estimate them. That violates the Paperwork Reduction Act.

The 2008 Final Rule is not required by law – indeed, it is almost certainly an illegal exercise of rulemaking authority. Without an OMB Control Number, the PTO cannot legally enforce it. Before OMB can even consider granting the PTO an approval that covers this provision, however, the PTO must acknowledge that the burdens exists and, for the first time, produce credible, objectively-based burden estimates for the steps applicants will take in response, and allow the public a reasonable opportunity to review and comment on them.

IV. Conclusion

This ICR should be disapproved, or should be approved with terms of clearance covering only the burden arising under 2004 appeal rules (except for the duplicative burdens, and those burdens the PTO imposes in violation of the Final Bulletin for Agency Good Guidance Practices). Only after the PTO has fully complied with the Paperwork Reduction Act should it be permitted to even seek OMB approval of the burdens in the 2008 Final Rule.

OMB should remember that the PTO's 2007 rule sharply limiting continuation practice – enjoined but now under appeal to the Federal Circuit – envisioned appeals as the preferred way for applicants to seek remedies from improper examiner decisions. The 2008 Final Rule fundamentally altering the appeals practice betrays the PTO's fundamental dishonesty, for this rule would destroy appeals as a practical alternative. The PTO did not provide objectively based estimates of the burdens for that rule either. The relevant ICR (0651-0031) has been "under review" at OMB for 14 months, with no

¹⁶ In *Tafas v. Dudas*, 541 F.Supp.2d 805, 817, 86 USPQ2d 1623, 1632 (E.D. Va. 2008), the Court specifically held that rules that shift burdens of proof are outside the PTO's rulemaking authority. The PTO's going final with another shift of burden of proof only two months later suggests that the PTO's rulemaking and legal oversight functions may be malfunctioning.

sign that the Patent Office is the least bit interested in obtaining honest burden estimates.

The difference is that the PTO has an OMB Control Number for 0651-0031 and OMB continues to issue 30-day extensions. So the Patent Office has no incentive whatsoever to do anything constructive. If OMB issues a Control Number for 0651-00xx, the PTO will learn that aggressive and persistent refusal to comply with the Paperwork is an effective bureaucratic strategy.

Sincerely,

/s/ David E. Boundy

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