REGULATORY CHECKBOOK

26 June 2012

Mr. Jeffrey Zeints
Acting Director
Office of Management and Budget
Washington, DC 20503

Subject: **Eight Recently Proposed U.S. Patent and Trademark Office Regulations Misclassified by OMB as Merely "Significant"**

Dear Director Zeints,

The Administration has pursued an extended program to review existing regulations with an eye to revise or eliminate those that are duplicative or no longer serve their purpose.[1] Simultaneously, the crucial role of effective centralized regulatory review has been reiterated, with particular attention to the importance of regulatory impact analysis for economically significant draft regulations.[2] Meanwhile, President Obama has established an ambitious agenda making the protection of intellectual property a key element of economic renewal.

These objectives have come into stark conflict. A group of regulations recently proposed by the U.S. Patent and Trademark Office (USPTO) to implement the Leahy-Smith America Invents Act (AIA)[3] appear to have escaped effective OMB oversight, at least in part because they were misclassified by the USPTO as merely "significant." It is virtually certain that most (and possibly all) of these rules will have billions of dollars per year in economic effects. Obviously, this greatly exceeds the $100 million threshold for an "economically significant" regulatory action.[4]

As you know, classification as "economically significant" triggers the requirement to prepare a Regulatory Impact Analysis (RIA)[5] and presumptive designation by OMB as "major" under the Congressional Review Act.[6] Evading the economically significant/major designations is valuable to an agency that does not want to prepare an RIA or face the more rigorous

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[1] Obama (2011), Section 6.

[2] Ibid., Section 1(c).

[3] Pub. L. No. 112-29, 125 Stat. 284 (2011).

[4] Supporters and opponents of the AIA and regulations implementing it agree on very little, but they do agree that the economic effects will be very great. See, e.g., Kesan (2012), Rantanen and Petherbridge (2012b), Rantanen and Petherbridge (2012a).

[5] Clinton (1993) Section 6(a)(3)(C).

[6] 5 U.S.C. § 804(2).

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scrutiny that OMB and Congress devote to economically significant/major regulations.

There are several possible reasons why OMB might have failed to recognize the magnitude of effects these proposed rules are expected to have on the U.S. economy. For example, each was misclassified by the USPTO. OMB staff may have placed too much reliance on the USPTO's good-faith compliance with Executive Order 12866. Alternatively, OMB staff might not have realized that the USPTO withheld material information about the magnitude of likely economic effects.

However, these actions alone do not seem to be sufficient to explain why OMB concluded review without classifying these rules properly.[7] First, the purpose of the AIA was to fundamentally restructure the U.S. patent system. It should go without saying that regulations implementing a statutory change of such magnitude are inarguably economically significant.[8] But this does not exempt from regulatory impact analysis; OMB Circular A-4 specifically recommends ways to ensure that economic effects resulting from statutory changes be distinguished from economic effects resulting from the exercise of administrative discretion.[9]

Second, agency strategic behavior leading to misclassification is hardly new or such a rare event that the experienced OMB staff would not be aware of the telltale signs. For one of these rules, the USPTO acknowledged $209 million in new annual paperwork burdens just two paragraphs after asserting that the draft proposed rule was merely "significant" (i.e., having likely economic effects less than $100 million)[10] It is hard to imagine how OMB missed this obvious contradiction.

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[7] Executive Order 12866 § 6(a)(3(B) gives OMB has the authority to overrule erroneous agency erroneous classifications. The Administrator of OMB's Office of Information and Regulatory Affairs has the sole authority to designate rules as "major" under the Congressional Review Act § 804(2).

[8] OMB has instituted recordkeeping to enable regulations implementing the Patient Protection and Affordable Care Act and Dodd-Frank Wall Street Reform and Consumer Protection Act to be clearly distinguished from other regulations. See http://www.reginfo.gov/public/do/eoAdvancedSearchMain.

[9] Office of Management and Budget (2003) E.g., regarding the selection of the analytic baseline: "In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action."

[10] See U.S. Patent and Trademark Office (2012), p. 6902. Compare bottom of col. 2 (proposed rule is "significant," but not "economically significant") and top of col. 3 (proposed rule has an estimated $209 million in annual paperwork burdens). The USPTO provides no estimates of economic effects.

Third, OMB's willingness to allow the USPTO to fundamentally mischaracterize social costs as paperwork burdens only, and provide no estimates whatsoever of effects on the U.S. economy or its major sectors, is deeply troubling. Even if it is assumed that there were good policy reasons for OMB not to perform a rigorous substantive review of these rules, there is no policy justification for failing to ensure that likely economic effects were honestly portrayed. Adding insult to this analytic injury, OMB also allowed the USPTO to give itself credit for certain paperwork burdens that Congress, not the USPTO, eliminated by statute. OMB review is supposed to ensure, at a minimum, that agencies do not mislead the public concerning the likely effects of regulation. For each of these eight proposed rules, OMB review failed abysmally.

Finally, the absence of an RIA conflicts with every material provision of President Obama's Executive Order 13563. Competently performed regulatory analysis is a prerequisite for the public to participate effectively (§ 2); for ensuring that multiple, complex regulations are integrated to reduce costs (§ 3); and for enabling the USPTO to adopt regulatory approaches that reduce burdens while maintaining flexibility and freedom of choice (§ 4). Whereas the President has directed agencies to ensure the objectivity of any scientific and technological information and processes used to support their regulatory actions (§ 5), the USPTO's method of compliance appears to be to avoid disclosing information in the first place. Under these conditions, it is impossible for the USPTO to adhere to any of the President's regulatory principles (§ 1(b)), except by accident.

Left unaddressed, as soon as July 2012 the USPTO is expected to publish these economically significant NPRMs as final rules, but without the benefit of even rudimentary RIAs to inform reasoned decision making. Regulatory impact analysis is key to the Administration's campaign for "smart" regulation, for "smart" regulation is infeasible without it.

Fortunately, a simple remedy is available. First, OMB can and should immediately reclassify these regulations as economically significant and publicly direct the USPTO to prepare a comprehensive RIA that adheres to the principles and standards of OMB Circular A-4,[11] preferably prior to promulgation.[12] If, in OMB's judgment, a meaningful RIA cannot be

[11] Office of Management and Budget (2003). Circular A-4 provides for situations such as this in which much (but not all) of the costs, benefits, and other economic effects are the result of statutory provisions: "When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement."

[12] The USPTO began soliciting public comment on the issues presented by these rules immediately after the law was signed in September 2011. It began lobbying for the underlying statutory changes years before that. Thus, the Office had plenty of time to conduct a

completed in time for the agency to meet its statutory deadlines, Executive Order 12866 § 6(a)(3)(D) provides that agencies shall comply with these analytic requirements to the extent practicable even if compliance is delayed beyond the date of promulgation. Timely compliance to inform decision making is always best, but even late compliance provides an opportunity to perform the retrospective review (see EO 13563 § 6) that will be needed to clean up the mess if only "dumb" regulations can be promulgated by the statutory deadline.

Second, as OMB knows, the USPTO intends to promulgate additional tranches of economically significant regulations in late 2012 and early 2013. OMB should immediately exercise its authority to properly classify all future USPTO regulations as economically significant while there is still enough time to competently prepare an RIA.[13] By correctly classifying these rules now, OMB can signal to the USPTO that it is expected to adhere to the same procedures and meet the same analytic requirements that for decades have applied to other federal agencies. Of course, if OMB believes that the USPTO deserves to be exempted from these requirements, it should say so directly and clearly state the basis for granting it such an exemption.[14]

These actions would go a long way toward remedying what has become a chronic problem for OMB. Having established a practice of reviewing USPTO regulations through benign neglect, it has incentivized the Patent Office to evade compliance with procedures and practices that other federal agencies seem to be able to manage without trauma. Unless and until OMB gets serious about USPTO oversight, the Patent Office will continue to create a host of problems for the Administration and undermine the President's intellectual property agenda.

I have enclosed a more detailed analysis showing how these eight proposed rules illustrate systematic misclassification and why it undermines the President's "smart" regulation agenda. Regulatory impact analysis is

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comprehensive RIA prior to publishing these proposed rules. I realize that much time has been lost due to the USPTO's decision not to abide by § 6(a)(3)(C), which OMB has enabled through ineffective oversight.

[13] Clinton (1993), Section 6(a)(3): "In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion…" This includes the preparation of RIAs for economically significant regulations, as defined in § 6(a)(3)(C).

[14] The authority to exempt agencies is contained Executive Order 12866 § 6 ("The guidelines set forth below shall apply to all regulatory actions … by agencies other than those agencies specifically exempted by the Administrator of OIRA," emphasis added) and § 6(a)(3)(B) ("The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant"). The Administrator did not waive review of any of these proposed regulatory actions and has not exempted the USPTO from § 6.

essential for "smart" regulation, not optional. When RIAs are not prepared, "smart" regulation isn't even feasible.

The USPTO has evaded the requirement to prepare RIAs since at least 1993, and possibly since it was first established in 1981. Unfortunately, OMB has contributed to the problem by failing to subject USPTO rulemaking to regulatory oversight that befits the magnitude of its regulatory actions.

Sincerely,

Enclosure: "How Regulatory Misclassifications by the U.S. Patent and Trademark Office and Office of Management and Budget Undermine 'Smart' Regulation

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REGULATORY CHECKBOOK

How Misclassifications by the U.S. Patent and Trademark Office and Office of Management and Budget Undermine "Smart" Regulation

Richard B. Belzer, Ph.D.

26 June 2012

When President Obama signed Executive Order 13563 in January 2011, he emphasized the importance of promulgating "smarter" regulations—regulations that reflect a modernized approach that is "cost-effective, evidence-based, and transparent to the public."[1] To make regulations smarter, however, requires the aggressive use of rigorous, competently-performed regulatory impact analysis. The requirement to prepare Regulatory Impact analyses (RIAs) has been in place since 1981, and for some agencies it has become a routine part of their regulatory development process. When an RIA is not performed, it is impossible for an agency to design a regulation in ways that adhere to President Obama's directive.

Not all federal agencies comply with the directives of President Obama or his predecessors. Some devote prefer to evade the requirement to prepare RIAs. One way this is done is by misclassifying regulations so that RIAs are not required. Since 1993, only "economically significant" regulations have been required to have RIAs. Thus, an agency wishing to avoid having to prepare an RIA need only misclassify its regulations as merely "significant."[2]

This paper provides a detailed look at how one particular agency—the U.S. Patent and Trademark Office—persists in systematically misclassifying "economically significant" regulations as merely "significant" in order to evade the RIA requirement. The context is a set of eight proposed regulations beginning to implement the Leahy-Smith America Invents Act

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[1] Lipton (2010), Obama (2011b), Obama (2011a), Rushing (2011).

[2] A "significant" regulation is a routine one—not so mundane that OMB review isn't needed, but not so important that an RIA is required. For FYs 1994 through 2011, OMB reviewed 11,628 draft regulations, or about 650 per year. Approximately 15% of them were classified as "economically significant" and thus subject to the RIA requirement. These statistics come from reginfo.gov, OMB's online database of its regulatory review and Paperwork Reduction Act activities. The database does not reveal how many of the 1,764 economically significant regulations were accompanied by RIAs.

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(AIA). The USPTO is an appropriate study subject because, as shown in Section III, the subject matter of USPTO regulations is purely economic, thus lacking the inherent complexities and controversies of regulation to manage health, safety, or environmental risks, and because the USPTO' compliance with longstanding requirements for regulatory impact analysis has been consistently and abysmally below applicable standards. When draft regulations are misclassified to evade the RIA requirement, the ability to craft "smart" regulations is lost. Because they systematically lack RIAs, there is every reason to believe that these regulations will fall egregiously short of the President's objectives.

This would not occur if OMB devoted an appropriate share of its review resources to the USPTO. It doesn't. OMB has instead established a pattern of either willful neglect or collaborative enablement. Though OMB has the authority to classify rules as economically significant, it apparently has never exercised this authority with respect to USPTO rulemaking. While it is certainly possible that OMB staff have been misled by the USPTO over the years, OMB has not exercised its authority to properly classify regulations even after having become aware of their economically significant effects.

Section I identifies eight regulations recently proposed by the USPTO that are either certain or extremely likely to be economically significant. All were misclassified by the USPTO to evade the RIA requirement, and none of them were accompanied by even rudimentary economic analysis. When the USPTO promulgates these rules as final, the absence of RIAs means they will not be "smart" regulations.

Section II explains why even seemingly trivial regulatory actions taken by the USPTO have economically significant effects. Intellectual property is a crucial attribute of a broad range of sectors in the U.S. economy. According to the government, patent-intensive industries contribute almost 4 million jobs and more than 5% of the Nation's gross domestic product. Very small changes in USPTO regulations, guidance, and internal practices have extraordinarily broad and deep effects on the U.S. economy. Just a 2% increase in aggregate paperwork burden—much less than the error bounds of the USPTO's burden estimates—is sufficient to exceed the $100 million threshold for economic significance.

Section III expands the indictment by showing that the evasion of Executive Order 12866 and its RIA requirement is a longstanding USPTO practice. Of 65 draft final regulations reviewed by OMB since 1993, only two of them were properly classified as economically significant. If an RIA was performed for either of them, it cannot be easily located.

Section IV provides three recommendations for OMB. First, it should immediately reclassify the eight recently proposed regulations as economically significant. The USPTO may not be able to competently prepare an RIA for these regulations prior to the September 2012 statutory deadline,

but it can be put on a schedule to complete one before billions of dollars of damage are done to the U.S. economy merely because the Patent Office has no interest in "smart" regulation.

Second, OMB should pre-emptively designate all future USPTO regulations as economically significant and subject to the RIA requirement. If and only if the USPTO can credibly show that a proposed rule is not likely to be economically significant should the regulation be reclassified as merely "significant." This showing must be confirmed through full disclosure, notice, and public comment, not a mere certification by Patent Office officials.

Third, OMB should reallocate its resources to significantly intensify its oversight of the USPTO. The President's ambitious intellectual property agenda cannot be achieved if the USPTO continues to escape performing the economic analyses necessary to show that its regulations are consistent with this agenda. That outcome is inevitable if OMB continues to refrain from performing effective oversight.

I. Eight Recently Proposed U.S. Patent and Trademark Office Regulations Misclassified by OMB

Each of the eight economically significant proposed rules misclassified by USPTO and OMB is briefly summarized below. In the next section, I show that the USPTO's cavalier noncompliance with Executive Order 12866 is an ingrained agency practice, one that President Obama's Executive Order 13563 has utterly failed to dislodge.

A. *"Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions"*[3]

The "Rules of Practice" NPRM would establish agency procedures for proceedings before the USPTO's Board of Patent Appeals and Interferences, now reinvented as the Patent Trial and Appeal Board. Even though its officials are called "judges," the Board is not a court; rather, it is the highest internal agency patent examination authority. Historically, the Board's primary responsibility was to resolve disputes over patentability between applicants and USPTO examiners. The AIA seeks to shift a significant fraction of all patent litigation from Article III courts to the reinvented Board, which will now have the responsibility of resolving disputes between patent holders and third party challengers, most of whom are accused infringers. This is an enormous expansion in agency responsibility, one for which there is no precedent in the patent system, and perhaps not anywhere else in government.

[3] U.S. Patent and Trademark Office (2012g).

1. Even procedural regulations can have economically significant effects

By law, this rule can only be procedural because Congress did not delegate to the Patent Office any authority to promulgate substantive regulations. Nonetheless, procedural rules can have substantial economic effects, and sometimes substantive effects as well.[4] A hint that this proposed rule would have significant economic (and perhaps substantive) effects is self-evident in the USPTO's preliminary estimate of incremental annual paperwork burdens: $209,131,529 for FY 2013 (with no estimates provided for FYs 2014 and 2015). Of course, if an agency expects a proposed rule to impose $209 million in annual paperwork burdens for a voluntary procedure, it is impossible to escape the inference that those who invoke the procedure expect the economic effects to be many times greater.

2. Regulatory impact analysis is especially important to distinguish the effects of statutory changes from the effects of agency discretion

Certain provisions of this proposed rule go beyond what the AIA requires, thus making them particularly ripe candidates for regulatory impact analysis. For example, proposed § 42.73 appears to be an attempt to deny applicants certain rights established in 35 U.S.C. § 120. Applicants that have a statutory right to file a continuation application cannot be denied these rights by regulatory estoppel. Also, § 42.73(3)(ii) appears to require patent applicants to contemplate all possible issues that might be raised or resolved in a subsequent post-grant proceeding, and preemptively file claims to meet each contingency. Whatever the merits of a regulatory requirement for clairvoyance, only regulatory impact analysis would make its costs and benefits transparent.[5] Regulatory impact analysis is needed to sort out how § 42.73 would work within the constraints of 5 U.S.C. § 120.

3. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

The USPTO provides no analysis whatsoever of the economic effects of the PGR proposal. There is a short discussion in the "Executive Order 12866" section of the preamble of "several benefits" that the Office expects.[6] Characteristically for the Patent Office, the benefits it mentions (and only

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[4] The substantive effects of the USPTO's 2007 Claims and Continuations Final Rule (RINs 0651-AD93 and 0651-AD94 promulgated together) were the proximate reason why the rule was overturned and vacated. See Tafas v. Dudas (2008).

[5] Other provisions in this proposed rule have been cited as exceeding the statutory minimum, and thus are important candidates for inclusion in an RIA. See, e.g., Baluch (2012).

[6] U.S. Patent and Trademark Office (2012g), pp. 6902-6903 .

qualitatively) are mostly cost reductions that the Office itself hopes to realize. With respect to the public, patent-intensive sectors of the economy, or the economy as a whole—the primary focus of Executive Order 12866—the USPTO identifies no social costs, no social benefits, and no transfers. The Patent Office claims that its rules will have the qualitative benefit of more timely decision making than what the courts can achieve, thus reducing overall transactions costs, but even these benefits appear to be counterfactual. Existing law imposes a similar requirement for timeliness in the adjudication of *inter partes* reexaminations that the Patent Office has not remotely achieved. Indeed, the Patent Office has proved to be an even slower forum for resolution of these issues than the courts.

In lieu of elementary honesty, the USPTO makes a novel but disingenuous attempt to rationalize its failure to properly designate this proposed rule as economically significant. The Office identifies $129 million in paperwork burden that it believes was eliminated by the AIA, which it treats it as a "credit" against the $209 million in acknowledged paperwork burden attributable to this rule.[7] Thus, according to the preamble to the NPRM, the "aggregate burden of the proposed rule[] for implementing the new review proceedings would be $79,201,129 ($209,131,529 minus $129,930,400) in fiscal year 2013," which of course is less than $100 million.[8]

It is hard to know if this chicanery is unprecedented given the historic scope, scale, and persistence of federal agency attempts generally to evade designation of rules as "major"[9] or "economically significant."[10] Regardless, the USPTO's manipulation of paperwork burdens is incompatible with logic, law, and the clear text of Executive Order 12866 and OMB Circular A-4. Logic and the Paperwork Reduction Act forbid the USPTO from giving itself credit for burden reductions enacted by Congress.[11] Executive Order 12866

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[7] USPTO estimates of paperwork burden are highly suspect. The Office has a longstanding practice of intentionally underestimating paperwork burden; it fails to correct obvious errors even after being alerted to them, and recently denied an Information Quality Act request for correction on the fanciful ground that burden estimates are exempt from OMB's definition of "information." See Belzer (2012), pp. 4-6.

[8] U.S. Patent and Trademark Office (2012g), p. 6903.

[9] Reagan (1981), Section 1(b). See also Congressional Review Act, 5 U.S.C. § 804(2).

[10] Clinton (1993), Section 3(f)(1); see discussion of USPTO longstanding noncompliance in § III.

[11] OMB procedures implementing the Paperwork Reduction Act require changes in burden to be allocated among the following categories: (1) changes due to new statute, (b) changes due to agency discretion; (c) changes due to adjustment in estimate, and (d) changes due to potential violation of the Paperwork Reduction Act. It is inappropriate for the USPTO to misclassify, and it would be impermissible

§ 6(a)(3)(B)(ii) concerns "economic effects," which OMB Circular A-4 describes as costs, benefits, and transfers. Circular A-4 advises against ignoring paperwork burdens, but they are not its focus. The USPTO, however, counts ancillary paperwork burdens but ignores far larger economic effects, the effects on business and patent-mediated investment flows.

The USPTO's decision to practice analytic subterfuge is readily explained by its bureaucratic desire to avoid the burden and threat of performing a Regulatory Impact Analysis, as Executive Order 12866 requires. Performing an RIA is burdensome to the USPTO because it cannot be performed for free. An RIA is threatening because it could expose material errors in the Office's justification for the rule.

B. *"Changes to Implement* Inter Partes *Review Proceedings"*[12]

The AIA directed the USPTO to establish procedures for a new program of *inter partes* review (IPR), which along with post-grant review (PGR) are new mechanisms allowing third parties to contest the validity of issued patents.[13] The twin predicates for these statutory provisions are, first, the fact that the USPTO inevitably issues some patents in error; and second, the belief that the USPTO can resolve these disputes with the same accuracy but less cost than the courts. Whatever the merits of these predicates, this proposed rule is certain to have economic effects exceeding the threshold for economically significance.[14]

IPR and post-grant review (PGR) replace an existing procedure for *inter partes* reexamination that has essentially the same predicate—the Patent Office sometimes issues patents that it should not, and there ought to be a systematic way to correct these errors after the fact. However, the existing program for *inter partes* reexamination appears to have been a failure. The 1999 law that directed the creation of *inter partes* reexaminations required the USPTO to conclude them with "special dispatch." However, a highly regarded 2008 study found no instance of a fully-contested *inter partes* reexamination that had reached a conclusion during the program's eight years in operation. The authors predicted that instead of achieving resolution with "special dispatch," the average pendency of a contested case would be 6.5 years.[15] Whether the result of implementation

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for OMB to allow, burden reductions due to statutory change to be mischaracterized as changes due to agency discretion.

[12] U.S. Patent and Trademark Office (2012b).

[13] The proposed post-grant review (PGR) rule is discussed in the following subsection.

[14] Profound economic effects are widely expected. See, e.g., Phillips and Laurence (2010)("The newly proposed post-grant and inter partes review proceedings promise to drastically change the landscape of post-grant proceedings").

[15] Eckardt and Blaxill (2008). The 95th percent confidence interval was five to eight years.

problems within USPTO or petitioner strategy, delay appears to have become a predictable characteristic of post-grant review, one that the USPTO would have to overcome by regulatory design. The absence of a regulatory impact analysis essentially ensures that the Patent Office will fail again.

1. This regulation, either alone or in combination with the PGR rule, is likely to have annual economic effects well in excess of $100 million[16]

Whether the IPR rule has any potential social benefits is unclear.[17] However, it will produce substantial economic effects in the form of rent transfers from patentees to post-grant challengers. Some of these rent transfers will be justified on the merits; others will not. Rent transfers will occur early—first, when petitions for review are filed; and second, when the USPTO approves them. The economic effects of subsequent judgments would be marginal if the market predictions of how the USPTO will act are accurate.[18]

Economic effects will differ by the nature of the post-grant challenge and how reviews are resolved. Judgments favorable to challengers, irrespective of merit, transfer wealth from the original patent owner to the challenger. There will be social costs associated with effecting these transfers, but little or no social benefits apart from the possible intangible benefits of justice, assuming that judgments are not predictably in error on the merits. The benefits to a patentee of surviving a meritless IPR are even harder to imagine, though some commentators have tried to think of some.[19]

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[16] Splitting an economically significant rule into multiple significant rules does not eliminate its economic significance.

[17] For an expression of confidence that the USPTO can manage post-grant challenges at less cost than the courts, thus reducing transactions costs, see Kesan (2012), p. 235. As for social benefits, Kesan takes the view that they are possible because the AIA removes a government failure resulting from informational asymmetries disadvantaging the USPTO vis-à-vis applicants: "By bringing people with knowledge about the invention at issue into the process, the AIA increases the likelihood that the patent claims that are granted are commensurate with innovation." The same could be said about the existing *inter partes* reexamination procedure, the effectiveness and efficiency of which are suspect. Moreover, the jury is out as to whether the social benefits of improved patent quality due to post-grant review exceed the social costs of sham petitioning. Regulatory impact analysis would be useful for approximating the procedural rules that maximize net social benefits, or at least minimize net social costs.

[18] The accuracy of market predictions is not necessarily correlated with the merits of USPTO judgments. Market uncertainty would be absent, for example, if the USPTO always ruled for or against patentees.

[19] See, e.g., Kesan (2012): "From the patentee's perspective, a successful post-grant review provides one of the best indicators of value for all actors who may be interested in or affected by an issued patent." The argument seem to be less

2. Cursory USPTO standards for initiating post-grant review reduce the value of all patents and encourage sham petitioning, exacerbate its social costs

In FY 2009, the USPTO granted 94% of petitions for *inter partes* reexamination,[20] and the Office expects to approve 93% of IPR petitions—an indistinguishable difference.[21] This means that the Patent Office historically has not performed anything more than a cursory evaluation before deciding whether to initiate post-grant review. And the Patent Office does not expect this to change, even though the burden of proof on the petitioner under the AIA's new procedures is said to be significantly more stringent such that the approval rate ought to decline.[22]

Economic effects are first realized when a petition is filed or investors learn that filing is imminent, largely because filing has been tantamount to USPTO approval. Social costs, including attorney fees and uncertainty about the patentee's business, are assured to occur early as long as the Patent Office essentially rubber stamps requests for review. That means the proposed IPR rule at least tolerates, and appears to subtly encourage, the filing of sham petitions by third parties who would strategically use post-grant review to damage business rivals or improve their negotiating position vis-à-vis licensing agreements.[23] Merely petitioning for IPR or PGR can result in devastating losses because it casts doubt about a patent's ultimate status and discourages the consummation of licensing agreements.[24] Regulatory

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economic than Nietzschean ("Was mich nicht umbringt, macht mich starker", "That which does not kill makes me stronger").

[20] Footnote 91 in Mercado (2011), p. 110, Rantanen and Petherbridge (2012).The USPTO appears to believe that AIA *inter partes* reviews will be so similar to pre-AIA *inter partes* examinations that the Office assumes the paperwork burdens of the former will be identical to the latter. See U.S. Patent and Trademark Office (2012b), p. 7055.

[21] U.S. Patent and Trademark Office (2012b), p. 7055. This high rate of approval is inconsistent with the notion, advanced by both AIA proponents and opponents, that the AIA's threshold for initiating *inter partes* or post-grant review are stringent. See Kesan (2012), p. 237, Rantanen and Petherbridge (2012), p. 242.

[22] Compare the criterion to initiate pre-AIA *inter partes* reexaminations ("substantial new question of patentability") with the criterion to initiate post-AIA *inter partes* reviews ("reasonable likelihood that the petitioner would prevail"). The latter standard appears to be widely regarded as less favorable to petitioners. See, e.g., Phillips and Laurence (2010).

[23] Mercado (2011) See also Rantanen and Petherbridge (2012) "[P]erhaps the main consequence of the [IPR and PGR] provisions will be to provide those with market power better means to clip the wings of up-and-coming competitors and to appropriate the value of their innovations."

[24] See, e.g., Avistar Communications Corporation (2008). After six months of licensing negotiations, all 29 of its U.S. patents were challenged under *inter partes* reexamination. The company reporting having to reduce its workforce by 25%.

impact analysis is essential for informing the design of the IPR rule to minimize sham petitioning.

This is obviously a particular concern for small-entity patentees. They may be especially vulnerable to predatory challenges and face extraordinary pressure to settle with petitioners for reasons other than the merits under patent law. Presumably, Congress did not intend for the USPTO to establish a regime that encourages or incentivizes predation by large entities, but only competently performed regulatory analysis can reveal which alternative regulatory designs encourage or ameliorate it.

For the IPR rule to produce social benefits it must reduce the propensity of the USPTO to issue invalid patents so that fewer, not more, meritorious IPR requests are filed. Indeed, the rule would generate still more social costs if it incentivized the USPTO to issue more invalid patents, knowing that errors could be corrected through IPR or PGR. Competently performed regulatory impact analysis can be helpful for designing procedures that encourage only meritorious requests for IPR and penalize sham petitioning.

3. A small number of IPR requests will be sufficient to make this rule economically significant

Leaving aside the value of paperwork burdens, it is clear that a mere handful of IPR challenges would be sufficient to yield more than $100 million in annual economic effects.[25] Suppose, for example, that the average value of an issued patent is $300,000.[26] The USPTO issued 244,000 patents in FY 2011, so the aggregate value of a year's patents would be about $70 billion. The $100 million threshold for an economically significant regulatory action would be exceeded if third-party challenges transferred or destroyed the economic value of only 700 of these 244,000 patents. Of course, the likelihood that a patent will be challenged rises with its value, so the average value of patents challenged under IPR would be higher. Suppose that the average value of challenged patents is $1 million. If challenges transferred or destroyed the economic value of just 100 of 244,000 patents, that would be sufficient to produce $100 million in annual economic effects.

Subsequently, the company sold its patents to a closely held firm in which the company that challenged Avistar's patents is a major investor.

[25] As noted above, an *inter partes* review petition need not be successful on the merits to have substantial economic effects, including devastating losses to a rival. Indeed, from the perspective of a sham petitioner the best outcome may be one in which the USPTO never reaches a decision on the merits. A properly performed RIA would count social costs as they are realized, and a large share of these costs could be realized when petitions are filed, not when they are decided.

[26] This figure is rounded down from Bessen and Meurer (2008).

More broadly, the value of all issued patents is reduced to the extent that IPR creates generalized market uncertainty about the economic value of patenting. At the margin, this discourages investment in innovation and reduces the number of applications filed. Both changes are socially beneficial only if the specific intellectual property put at risk has only marginal economic value. Thus, to minimize social costs, the IPR rule should be designed to target patents least likely to be valid. Regulatory targeting is one of the principal benefits agencies and the public gain from regulatory impact analysis. Of course, if no RIA is performed, then this social benefit is foregone.

4. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

Based on the preamble to the proposed rule it appears that the USPTO has conducted no regulatory analysis at all. The "Executive Order 12866" section of the preamble includes no discussion whatsoever of the rule's likely economic effects.[27] Instead, it includes only a perfunctory (and non-transparent) discussion of paperwork burdens very similar to the one published for the Rules of Practice NPRM.

The USPTO estimates the value of the incremental paperwork burden at $175 million for FY 2013.[28] For Executive Order 12866 purposes, however, the USPTO awards itself a "credit" of $120 million for the elimination of paperwork burdens associated with *inter partes* reexaminations. This reduces the apparent "cost" of the proposed rule to $54 million, which of course is less than the $100 million threshold for an economically significant regulatory action.

As I noted above for the Rules of Practice NPRM, there is simply no merit in, and no legitimate precedent for, an agency "crediting" itself for cost savings that may have been achieved by Congress. It also conflicts with more than 30 years of OMB practice in which "economic effects" means social costs, social benefits, and other effects such as transfers. Paperwork burdens are a component of social costs, to be sure, but they are usually incidental. When voluntary paperwork burdens amount to $175 million per year (or even $54 million per year), they are economic indicators of the likely presence of hundreds of millions or even billions of dollars in economic effects. Ignoring these effects is analytically illegitimate and deceitful.

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[27] U.S. Patent and Trademark Office (2012b), p. 7055.

[28] Ibid., No estimates are given for subsequent fiscal years.

5. Competently performed regulatory impact analysis is essential for "smart" regulation, which the Administration says it its highest value

Several aspects of the post-grant review problem, which apply to both the IPR and PGR rules, justify intensive analysis prior to promulgation. In particular, these new procedures invite mischievous strategic behavior on the part of some third parties, much like the pre-AIA *inter partes* reexamination program appears to have done, and it falls on the USPTO to craft procedural rules that minimize it. For example, Congress made clear that it expects the Patent Office to evaluate requests for post-grant review with a more critical eye than it did under the *inter partes* reexamination program. Analysis should be performed to illuminate the relative costs and benefits of alternative ways to implement the new, more stringent criterion for initiating review.

Similarly, the USPTO also could use its new fee setting authority to indirectly penalize unmeritorious requests. This could be done, for example, by significantly increasing the fee charged on requests for review with most of the proceeds refunded to the prevailing party.[29] The USPTO's failure to make any analytic effort makes it highly likely that the final IPR and PGR rules will fail to promptly resolve inter partes disputes (Congress' stated purposes) and fail to reduce transactions costs (the social benefit advertised by academic supporters), but it will not stop sham petitioning and other strategic behavior that has no conceivable social benefit.

C. *"Changes To Implement Post-Grant Review Proceedings"* [30]

Whereas IPR is available only for the limited circumstances in which a challenger alleges that the USPTO failed to properly recognize prior art, it can be sought at any time during a patent's life. PGR allows a wide range of grounds for challenge, but only for nine months after a patent issues. Because these attributes operate in opposite directions, the relative magnitudes of the two rules cannot be ascertained in advance.

1. This regulation, either alone or in combination with the IPR rule, is likely to have annual economic effects well in excess of $100 million

The USPTO assumes that there will be only 50 PGR petitions filed compared to 480 IPR petitions.[31] The basis for neither of these estimates is explained, however, nor does the USPTO account in its estimates for the

[29] Challengers with meritorious complaints would not be harmed, as they would receive refunds. Patentees subjected to unmeritorious challenges would benefit from challengers having to implicitly reimburse them the costs of defense.

[30] Bessen and Meurer (2008).

[31] Compare U.S. Patent and Trademark Office (2012b), p. 7057 [960/2], U.S. Patent and Trademark Office (2012c), p. 7077 [100/2].

rapid growth in third-party challenges via the *inter partes* reexamination procedure during the past decade. Meanwhile, the Patent Office acknowledges that it expects unit paperwork burdens to be about 30% greater for PGR than IPR petitions. So even a small understatement of the predicted number of PGR petitions would result in the paperwork burdens for the two rules being roughly the same, not different by a factor of seven.[32]

More importantly, as noted before, when voluntary paperwork burdens are counted in the tens of millions of dollars, they signal the existence of much larger economic costs. Absent strong and persuasive evidence to the contrary, the PGR rule should be classified as economically significant. The absence of agency estimates of economic effects is not evidence that they are absent.

2. Cursory USPTO standards for initiating post-grant review reduce the value of all patents and encourage sham petitioning, exacerbate its social costs

As noted in the discussion of the IPR rule, the USPTO expects to approve virtually all PGR petitions for review. Thus, the PGR proposal is susceptible to the same regulatory design deficiencies as the IPR rule. Too many unmeritorious reviews will be initiated, with concomitant social costs. Sham petitioning for strategic reasons will be tolerated, if not encouraged. Small-entity patentees will be disproportionately affected because of their limited ability to defend against strategic predation. And the value of all patents will be diminished during the nine month window in which PGR challenges are permitted. Regulatory impact analysis is needed to devise procedural rules that minimize these predictable but unintended consequences.

3. A small number of PGR requests will be sufficient to make this rule economically significant

Though the window for PGR challenges is short, the potential value to rivals of filing a challenge is especially great during this period. The targeted patentee will be just beginning the process of commercialization and licensing.

The $100 million threshold of economic effects may seem high, but it would take only few challenges of especially valuable patents to yield effects of this magnitude.

[32] The USPTO claims that the incremental paperwork burdens of the proposed PGR rule at $22,761,410. See U.S. Patent and Trademark Office (2012c), p. 7075. This figure cannot be independently validated because the Office did not disclose enough information about its derivation. Based on past USPTO practice, it is reasonable to assume that, these burdens are significantly underestimated. See footnote 7 and § III.

4. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

The USPTO provides no analysis whatsoever of the economic effects of the PGR proposal. There is a short discussion in the "Executive Order 12866" section of the preamble of "several benefits" that the Office expects.[33] Characteristically for the Patent Office, the only benefits it mentions (and only qualitatively) are cost reductions that the Office itself hopes to realize. As for the public, patent-intensive businesses and innovation, or the economy as a whole—the primary focus of Executive Order 12866—the USPTO identifies no social costs, no social benefits, and no transfers except the qualitative benefit of more timely decision making by the Patent Office than the courts, thus reducing transactions costs. As noted above for the Rules of Practice NPRM, the Patent Office claims that this rule will have the qualitative benefit of more timely decision making than what the courts can achieve, thus reducing overall transactions costs, but for this benefit to be realized, the Patent Office must achieve statutory goals that it failed to meet with respect to the similarly structured *inter partes* reexamination program.

D. "Changes to Implement Transitional Program for Covered Business Method Patents" [34]

The AIA directed the USPTO to establish a term-limited program to subject business-methods patents to special review upon request by a third party. This rule would establish the procedures for such reviews, with the accompanying "Definition of Technological Invention" NPRM (discussed in the next subsection) providing the substantive criteria.

Business-method patents comprise a bit over 2% of all patents granted over the past five years. Estimates are elusive but their market value appears to be substantial. Like the IPR and PGR proposed rules discussed previously, how the USPTO manages the process by which business-methods patents are challenged is crucial for establishing predictability and reducing uncertainty for this segment of intellectual property. One would expect a significant analytic effort devoted to understanding and valuing the many tradeoffs involved. If one harbored such expectations, however, one would be sorely disappointed by the USPTO's proposed rule and notice.

1. This regulation, either alone or in combination with the companion Definition of Technological Invention rule, is

[33] Ibid.,

[34] U.S. Patent and Trademark Office (2012h).

likely to have annual economic effects well in excess of $100 million[35]

Business-method patents may be a small percentage of all patents issued, and in some quarters they are controversial, but they represent an important driver of intellectual property growth and presumptive economic value, reported by commentators on both sides of the debate to be in the billions of dollars.[36]

Thus, it is exceedingly difficult to imagine any circumstances under which this rule, probably alone but definitely in combination with the "Definition of Technological Invention" NPRM, would not be economically significant.

2. Cursory USPTO standards for initiating post-grant review reduce the value of all patents and encourage sham petitioning, exacerbate its social costs

The preamble does not provide any indication how the Patent Office intends to decide whether to initiate review in response to petitions it receives. The Office does state that it expects to receive only 50 such petitions, leading to 100 respondents and 515 covered responses per year. The basis for these assumptions is not explained.

Given the disproportionate attention that has been devoted to business methods patents, and (as explained in the following subsection) total uncertainty concerning how the USPTO intends to make decisions, the Patent Office's estimates lack credibility. If it applies the same rule of thumb in initiating business method patent reviews as it expects to apply for post-grant reviews generally, then virtually all petitions for review will be approved. Third parties will have unbounded incentives to challenge these patents in hopes of either prevailing on the merits, such as that can be discerned a priori in a regime of case-by-case decision making grounded on circular criteria, or petitioning for review for the strategic purpose of damaging rivals or improving their negotiating position vis-à-vis licensing.

3. A small number of Covered Business Methods reviews will be sufficient to make this rule economically significant

Under this proposed rule, it will be open season on billions of dollars worth of business methods patents. Patents with the weakest claims might be more prone to challenge, but it is certain that patents with the highest values will rise to the top of the list. Only a small number of business methods patents need to be challenged for economic effects to exceed the $100 million threshold for an economically significant rule.

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[35] Splitting an economically significant rule into multiple significant rules does not eliminate its economic significance.

[36] See, e.g., Kesan (2002), Fisher (2010), Trout (2010).

Economic effects will be realized irrespective of the final disposition of patents that are challenged. The mere filing of a petition seeking review will have economic effects, the magnitude of which will depend on whether the market believes that filing is tantamount to USPTO approval to initiate review. Substantial economic effects will be realized even if every business method patent subject to challenge is ultimately vindicated.

4. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

Like the other proposed rules discussed above, the USPTO classified the Covered Business Methods" proposal as "significant" but not "economically significant." If this classification has any analytic basis, the USPTO withheld it from public review and comment. The "Executive Order 12866" section of the preamble contains no discussion whatsoever of social costs, social benefits, and other economic effects.[37] The USPTO says "several benefits" are expected to result from the rule, but the benefits cited qualitatively consist only of potential cost reductions to the Patent Office and reductions in transactions costs due to the statutorily-required timeliness of USPTO decision making relative to the courts. This assumption is counterfactual, as existing law imposes a similar requirement for timeliness in the adjudication of *inter partes* reexaminations, which the Patent Office has not remotely achieved. As under pre-AIA law, under post-AIA law, nothing happens when the USPTO fails to meet statutory deadlines for timely decision making.

The only social costs mentioned by the USPTO consist of paperwork burdens, the aggregate value of which the Patent Office states is expected to be $22,761,410 in FY 2013 (with no estimates for subsequent years).[38] This figure is exactly the same as the USPTO's estimate of incremental paperwork burdens for the PGR proposed rule—an impossible coincidence. In fact, the USPTO's paperwork burden estimates are identical only because they rely on exactly the same arbitrary assumptions, none of which are supported by any data, modeling, or other evidence.

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[37] U.S. Patent and Trademark Office (2012h), p. 7091. The only social costs mentioned at all are $22,761,410 in paperwork burdens. Amazingly, this is exactly the same estimated burden as the estimate for the proposed PGR rule. The likelihood that these burdens are identical is zero—hence the general belief that USPTO burden "estimates" are not estimates at all; they are simply made up.

[38] U.S. Patent and Trademark Office (2012e).

E. *"Transitional Program for Covered Business Method Patents—Definition of Technological Invention"* [39]

A key element of the procedures for the examination of business-methods patents and challenges made by third parties is the definition of "technological invention." The AIA excludes "technological inventions" from the scope of the business methods review, but left the definition of the term to the USPTO. Thus, the definition of "technological innovation" is crucial to both the implementation of the rule by the USPTO and any estimate of its economic effects.

1. This regulation, either alone or in combination with the companion Covered Business Methods review rule, is likely to have annual economic effects well in excess of $100 million[40]

In this proposed rule, the USPTO indicates its intention to make these determinations on a case-by-case basis, using criteria that have no precise definitions and would be expensive to litigate, thus maximizing uncertainty for both the challenger and the patentee.[41] Assuming that this approach withstands judicial scrutiny, its economic effects are necessarily substantial given the unbounded market uncertainty that results from minimizing regulatory clarity and maximizing administrative discretion.

The proposal also creates the conditions for generalized agency corruption. The Patent Office will be pressured (and tempted) to give special treatment to favored applicants, and to retaliate against applicants who seem to "cause trouble" for the Office, such as by filing public comments and attempting to hold it accountable.

2. A small number of Covered Business Methods reviews will be sufficient to make this rule economically significant

As indicated above, the preamble does not provide any indication how the Patent Office intends to decide whether to initiate review in response to petitions it receives. In addition, its preference for case-by-case decision making utilizing vague and subjective criteria ensure that perhaps every patent approved for review will be hotly contested, both during review and subsequently in court. Social costs that arise from litigation which a rule makes likely are cognizable as regulatory costs under Executive Order 12866.

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[39] U.S. Patent and Trademark Office (2012h).

[40] Splitting an economically significant rule into multiple significant rules does not eliminate its economic significance.

[41] U.S. Patent and Trademark Office (2012h), pp. 7096 and 7108. Proposed § 42.301(b) lists the following criteria: "whether the claimed subject matter as a whole recites a technological feature that is novel and unobvious over the prior art; and solves a technical problem using a technical solution."

3. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

In the "Executive Order 12866" section of the preamble, the USPTO asserts that this proposed rule is not economically significant.[42] Except for unsupported boilerplate statements cut-and-pasted from other preambles, there is no discussion of the rule's likely social costs, social benefits, and other economic effects. The text repeats the same estimated paperwork burdens and qualitative claims of agency cost reductions contained in the PGR proposed rule even though the rules are hardly identical.

F. *"Changes To Implement Derivation Proceedings"* [43]

This proposed rule would implement new procedures for so-called "derivation proceedings" required by the AIA. Derivation proceedings apply when two inventors file patent applications claiming the same invention, and the second filer believes that the first filer copied from him.

1. This regulation is likely to have annual economic effects well in excess of $100 million

Derivation proceedings are certain to be highly contentious and have substantial economic effects given their obvious capacity to transfer the value of intellectual property from a patentee to a challenger.[44] Additional economic effects can be expected if the challenger has disproportionate financial and legal advantages and thus enjoys the capacity to make derivation challenges for strategic, predatory reasons.

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[42] Ibid., p. 7105.

[43] U.S. Patent and Trademark Office (2012a).

[44] It is possible that the outcome of a derivation proceeding would be no transfer of rents from patentee to challenger. New 35 U.S.C. § 135(b) directs the Patent Trial and Appeal Board to "determine whether an inventor named in the earlier application derived the claimed invention from an inventor named in the petitioner's application and, without authorization, the earlier application claiming such invention was filed." Generally, such a determination would void the patentee's claims, not transfer them to the challenger. However, the Board also has the authority to, "in appropriate circumstances" "correct the naming of the inventor in any application or patent at issue." This could arise, for example, if the parties reach a settlement (§ 135(e)): "Unless the Patent Trial and Appeal Board finds the agreement to be inconsistent with the evidence of record, if any, it shall take action consistent with the agreement." The law does not expressly authorize the Board to transfer ownership of a patent from the patentee to the challenger, but it also does not prohibit the Board from doing so. Regardless of the Board's decision, however, it will have substantial economic effects.

2. A small number of petitions seeking derivation proceedings will be sufficient to make this rule economically significant

As will be the case for other post-grant review rules, only a handful of patents need to be approved for derivation proceedings for the rule to have economic effects exceeding $100 million in any one year. The USPTO says only 100 petitions will be filed, but the basis for this estimate is not disclosed. Even with that small number, the USPTO still estimates $12 million in paperwork burden; as noted previously, the Patent Office has a longstanding reputation for understating burdens.[45]

Half of these paperwork burdens will be purely voluntary—no one is required to file a petition seeking initiation of a derivation proceeding—and half will be semi-voluntary—patentees can choose not to defend their patents. The USPTO reasonably expects that every derivation proceeding will be actively defended, which means that the market value of the challenged patent will almost certainly exceed, and probably by a large factor, the sum of all paperwork costs plus litigation expenses.[46]

3. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

The "Executive Order 12866" section of the preamble contains no discussion of these economic effects despite their potential to be spectacularly large.[47] As in the other cases, the USPTO asserts that this rule is not economically significant based on no evidence or economic analysis. Indeed, just as in the other cases, the USPTO's discussion of economic effects includes no analysis at all of economic effects. The only social costs acknowledged by the USPTO are $12 million in paperwork burdens.

As in the case of other proposed rules in this collection, important margins for regulatory analysis are provisions that go beyond what the AIA requires. For example, proposed § 42.406 sets forth the requirements for the

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[45] Derivation proceedings will be different than interferences, which the AIA terminates. Nonetheless, the USPTO's unit paperwork burden estimate ($61,333) is substantially less than the alternative historical figure provided by a senior interference practitioner ($2 million), which he characterized as "relatively cheap." See Gholz (2011), Slide 9.

[46] If the value of the patent is less than the sum of paperwork costs plus expected litigation expenses, then the patentee and challenger are better off negotiating a settlement instead.

[47] U.S. Patent and Trademark Office (2012h), p. 7036. See also Boundy and Marquardt (2010), p. 34: "Even where there is some possibility of showing derivation, actually doing so is *terribly* expensive. Under current law, derivation proceedings are not common, but when they do arise, they are among the most expensive issues in patent law to decide" (emphasis in original).

content of a petition to initiate a proceeding. This imposes burdens above the statutory minimum, in part because some requirements have little to no practical utility. § 42.406(b)(3)(ii) requires a superfluous showing of claim construction. U.S. law has had derivation proceedings for over a century, and a construction showing has never been required in the past.

G. *"Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees"* [48]

This proposed rule would implement a new procedure established by the AIA allowing patent owners to request "supplementary examination." This provision was created to allow applicants that had misinformed the Patent Office—intentionally or unintentionally—to correct the misstatement, and do so without risking sanctions for inequitable conduct. The rule can be expected to weaken incentives for truthfulness and disclosure that applicants now exert during initial examination of their applications, which is likely to reduce patent quality by increasing the number of patents awarded improperly. The defense of inequitable conduct has long been important to those alleged to be infringers. By eliminating this provision, the AIA also disrupts the balances of the patent system by attenuating the value of this defense, with concomitant economic effects.

1. This regulation is likely to have annual economic effects well in excess of $100 million

The number of requests for supplemental examination that will be filed are admittedly hard to predict. The USPTO says it expects 9,560; it provides no objective support for either the magnitude or precision of this figure. Each submission is expected to be fairly demanding, however, requiring 135 hours of expensive attorney time. The USPTO's aggregate burden estimate exceeds $ 80 million per year, showing convincingly that the economic costs likely to result from the rule are well over the threshold for economic significance.[49]

2. A small number of requests for supplementary examination will be sufficient to make this rule economically significant

Even if the USPTO's burden estimate were correct, the threshold for economic significance would be exceeded if the average value of patents subject to these requests is just $2,100.[50] But the average change in patent

[48] U.S. Patent and Trademark Office (2012a).

[49] U.S. Patent and Trademark Office (2012d), p. 3678. All requests for supplementary examination will be voluntary.

[50] ($100 million - $80 million)/9,560 = $2,092.

value must exceed $8,400 just to make it cost-effective to bear the voluntary paperwork burden of filing a request.[51]

3. Absent or disingenuous "analyses" of economic effects do not comply with the letter or spirit of Executive Order 12866, or serve the public interest

In the preamble section titled "Executive Order 12866" the USPTO says this proposed rule is "significant" but provides no information at all about the rule's likely economic effects.[52] As noted above, it is inconceivable that patent owners would voluntarily bear $80 million in paperwork burdens to protect less than $20 million of patent value. Rather, it is certain that this proposed rule, like the others, is expected to have economic effects in the hundreds of millions or billions of dollars per year.

H. *"Practice Guide for Proposed Trial Rules; Request for Comments"* [53]

This regulatory action is peculiar, for the USPTO neither says it is a proposed rule nor describe it as guidance. The crucial distinction between a rule and guidance has been clearly and succinctly presented by OMB in § II(2) of its Bulletin on Good Guidance Practices:

> Each significant guidance document shall:
>
> …
>
> (h) Not include mandatory language such as "shall," "must," "required" or "requirement," unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.[54]

A look at the contents of the Practice Guide shows that it has significant regulatory content. It limits the ways patent applicants may comply with the proposed Rules of Practice as well as other proposed rules in the collection. For example, the Practice Guide describes "scheduling orders" setting mandatory deadlines, in terms that are binding on the public. These scheduling orders are not mentioned in any of the NPRMs; they appear only in the Practice Guide.

Each scheduling order has regulatory costs and potential regulatory benefits, and depending on how the USPTO implements the language, these costs and benefits (and other effects) could well be economically significant.

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[51] $80 million/9,560 = $8,368.

[52] U.S. Patent and Trademark Office (2012d), p. 3677.

[53] U.S. Patent and Trademark Office (2012f).

[54] Office of Management and Budget (2007), p. 3439.

While it is not obvious that these regulatory provisions by themselves are likely to have economic effects exceeding $100 million per year, there is no question that the Practice Guide, in combination with the proposed Rules of Practice, will have annual economic effects exceeding $100 million by a wide margin.

The Practice Guide is unique among the eight regulatory actions because it contains no "Executive Order 12866" section, no "Administrative Procedure Act" section, and no "Paperwork Reduction Act" section. It includes no discussion whatsoever of economic effects, and no estimates of paperwork burden even though paperwork burdens are clearly included in the scheduling orders. The Practice does not even acknowledge the existence of new information collection provisions, a fact that is obviously legally problematic.[55] How this passed muster at OMB, which also implements and enforces the Paperwork Reduction Act, is anybody's guess.

II. What Seem to Be Small Regulatory Actions by the USPTO Have Economically Significant Consequences

The USPTO is a substantial generator of economic effects via regulation, but few people outside of the patent community are aware of it. This is at least in part due to the complexity of the U.S. patent system and its rules, and the specialized skills of its denizens, few of whom are economists. But it is also in part due to USPTO's phenomenally successful effort to evade effective OMB review, as shown in § III.

Yet this ability is purely derivative; OMB is largely responsible for creating the Patent Office's capacity for stealth regulation because it devotes trivial resources to USPTO oversight. For that reason, regulations with much smaller aggregate effects, particularly regulations targeted at vanishingly small environmental and public health problems, attract much more attention from OMB.[56]

A. U.S. Patent and Trademark Office Rulemaking Has Pervasive Effects on the U.S. Economy

A report recently published by the Administration offers considerable insight into the vast capacity of the USPTO to promulgate regulations that

[55] The Paperwork Reduction Act forbid agencies from conducting or sponsoring an information collection without, inter alia, first obtaining a valid OMB Control Number. 44 U.S.C. § 3512 specifically protects the public from such actions.

[56] OMB's Office of Information and Regulatory Affairs allocates an entire branch of desk officers, plus economists and scientists, to the review of draft regulations submitted by the U.S. Environmental Protection Agency. This is logical given the scale of economic effects that result from some EPA regulatory actions. However, OIRA devotes less than one FTE desk officer and no economists to the review of draft USPTO regulations, despite the near certainty that every regulatory action the Patent Office proposes is economically significant.

impose much more than $100 million in economic effects without so much as breaking a sweat. According to the USPTO and the Commerce Department's Economics and Statistics Administration (ESA), vast reaches of the U.S. economy are dependent on intellectual property. The ESA and USPTO say that 26 patent-intensive industries accounted for 3.9 million jobs in 2010, a disproportionate percentage of which are college graduates, plus another 3.3 million supply-chain jobs, and $763 billion in value-added, or 5.3% of U.S. GDP.[57] In the executive summary, ESA and USPTO say their figures probably understate the true importance of patents and other intellectual property.[58]

Even seemingly minor tweaks of the USPTO's regime for patent examination can have profound effects on intellectual property values, investments in IP-related research and development, and employment. The $100 million threshold for an economically significant regulatory action is just 0.013% (~1/8,000th) of the GDP that the USPTO attributes to patent-intensive industries.

B. Small Changes in Paperwork Burdens Alone Are Sufficient to Exceed the $100 Million Threshold for Economically Significant Rulemaking

It is revealing that, in lieu of *bona fide* estimates of the likely economic effects of the eight proposed regulations, the USPTO only purports to estimate paperwork burdens. Even the estimates provided by the USPTO for these proposed rules are telling, for they range from about $20 million to $210 million per year and likely to be significantly understated. We know that these burdens are a fraction of economic effects cognizable under Executive Order 12866 because patent applicants bear them voluntarily in hopes of securing intellectual property protection that is essential for the realization of the social benefits of innovation. It makes no sense to expend tens to hundreds of millions of dollars on paperwork to obtain IP protection that is worth less than this amount. Further, all expenditures on paperwork are borne despite uncertainty about whether they will succeed in securing any IP protection at all. That means the expected value of IP embedded in patent applications that cost $100 million to prosecute must be a large multiple of $100 million.

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[57].Economics and Statistics Administration and U.S. Patent and Trademark Office (2012), pp. 40, 43, and 45.

[58] Ibid., p. vi: "Because all U.S. industries rely on IP to some degree, the statistics reported here for the sectors that use IP most intensively may tend to under-represent the broad impact of IP in the American economy. Moreover, the statistics reported here may not fully reflect the long-run economic benefits and costs of IP in promoting innovation and productivity growth. For example, while this report shows that employment in trademark-intensive industries is almost six times as great as employment in patent-intensive industries, it may be that the kinds of innovation protected by patents play a larger role in driving the long-run growth of productivity throughout the economy."

For this reason, it is virtually certain that the U.S. economy experiences more than $100 million in economic effects even when the USPTO tweaks its regulations ever so slightly. In previous comments to the USPTO, I have shown that an increase of about 2% in the Patent Office's estimate of aggregate paperwork burden for just 12 ICRs is enough to exceed the $100 million threshold for an economically significant rule. Yet 2% is well within the range of uncertainty in the USPTO's burden estimates. Indeed, a single error—the use of medians instead of means in the default value of patent attorney billing hours—understates aggregate burden by 12%. This error persists, even in the paperwork burden estimates for this collection of proposed rules, despite multiple requests for correction. Thus, the USPTO commits these errors intentionally, presumably for the purpose of deceiving the public about the true burdens it imposes.[59]

III. The USPTO Routinely Evades Presidential Directives Concerning Regulation and Regulatory Impact Analysis

The eight regulatory actions recently proposed by the USPTO are hardly unique in their disregard for regulatory analysis. If there is one thing that can be said about the Patent Office, its disregard for regulatory analysis is systematic and unyielding.

A. More than Thirty Years of Presidential Commitments to Informing Regulatory Decision Making with Regulatory Impact Analysis Do Not Appear to Be Shared by USPTO Leadership

In January 2011, President Obama reiterated general principles of regulation found in Executive Order 12866, which have been in place since 1993.[60] Implementing these principles requires competently performed regulatory impact analysis:

> In applying these principles, each agency is directed to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.[61]

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[59] See Belzer (2011), p. 12. When presented with an opportunity to correct this error pursuant to the Information Quality Act, the USPTO refused to do so based on the surreal argument that paperwork burden estimates are not statistical "information" within OMB's definition because they are uncertain. See Katznelson (2010), pp. 10-12 (seeking correction) and Tamayo (2011), p. 6 (denying that burden estimates are "information"). OMB is complicit in this misconduct, for the USPTO could not have responded as it did without OMB approval. All agency responses to IQA error correction requests are reviewed by OMB before they are transmitted by the agency to the petitioner.

[60] Clinton (1993), Section 1, Obama (2011a), Section 1.

[61].Obama (2011a), Section 1(c).

Under no circumstances would the "best available techniques to quantify anticipated present and future benefits and costs" consist of performing no economic analysis at all, yet this is standard practice for the USPTO.

The previous discussion of the eight recent USPTO proposed regulatory actions an unimpeachable case that Patent Office leadership has no detectable interest in allowing regulatory impact analysis to inform its decision making, as Executive Orders 12866 and 13563 require. Most (and perhaps all) of these proposed rules are certain to be economically significant in their own right. When considered together, however, there cannot be any doubt that they are economically significant as a package. Yet the USPTO has willfully misclassified them, presumably to evade the requirement to prepare an RIA, and OMB has chosen to enable and encourage this misconduct.

This is not new behavior. A review of the history of USPTO rulemakings under Executive Order 12866 shows that only two of 65 draft regulations reviewed by OMB were classified as economically significant.[62] There do not appear to be RIAs for either of these rules, let alone for the dozens of rules that the USPTO misclassified.

B. President Obama's Commitment to Retrospective Review of Existing Regulations Does Not Appear to be Shared by USPTO Leadership

Similarly undetectable is the Patent Office's enthusiasm for implementing President Obama's January 2011 directive to conduct retrospective analysis of existing regulations. The Patent Office's Preliminary Plan for Retrospective Analysis of Existing Rules is ambitious for what it promises—to "review all of its existing regulations that were deemed 'significant'…"[63] However, there is no public evidence that the Patent Office has made any attempt to finalize its plan, much less implement it.[64]

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[62] The two draft regulations classified as economically significant were draft proposed rules setting fees for FY 2009. See http://www.reginfo.gov, search for 0651-AC29. The fee increase in FY 2004, which was considerably larger, was not properly classified.

[63] U.S. Department of Commerce (2011).

[64] The USPTO's "look back plan" web page includes links to Executive Order 13563, two paragraphs describing the "preliminary plan" in vague terms but no actual link to it, a statement that the USPTO is "working on finalizing" the plan, empty links to public comments ("coming soon"), and no actual retrospective review plan. See http://www.uspto.gov/ip/rules/lookback.jsp. This web page has not been updated since August 2, 2011.

C. The USPTO Leadership's Commitment to Executive Order 13563 Is Too Weak to be Detected

In lieu of actual compliance with Executive Order 13563, the USPTO simply makes a series of boilerplate. The text below is taken from the preamble of the Rules of Practice proposal:

> The Office has complied with Executive Order 13563. Specifically, the Office has to he extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.[65]

None these claims is supported by evidence, and the USPTO used the same boilerplate text for each of the other proposed rules.[66] Meanwhile, OMB reviewed each of these draft regulations before publication and accepted this boilerplate in lieu of actual compliance. At least with respect to the USPTO, President Obama's Executive Order 13563 became a dead letter in less than one year—ironically, perhaps, at the hands of his own appointees.

D. The USPTO Has a Longstanding Propensity to Misclassify Economically Significant Rules to Evade Regulatory Impact Analysis Requirements

Since 2006, the USPTO has misclassified numerous economically significant regulations as "significant." In two cases, the USPTO misclassified economically significant regulations as "not significant"—meaning too minor

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[65] U.S. Patent and Trademark Office (2012g), p. 6903.

[66] U.S. Patent and Trademark Office (2012b), pp. 7055-7056, U.S. Patent and Trademark Office (2012e), p. 7091, U.S. Patent and Trademark Office (2012h), p. 7105, U.S. Patent and Trademark Office (2012a), p. 7036, U.S. Patent and Trademark Office (2012c), p. 7076.

to even warrant OMB review. Yet both of these rules were intended by the USPTO to fundamentally change patent applicants' incentives, and thus they were assured of having profound economic effects. Public commenters estimated that one of these "not significant" regulations would impose billions of dollars in annual paperwork burden alone. The USPTO hoped to reduce pendency, perhaps the most obvious evidence of its internal inefficiency, by placing caps on the complexity of inventions it would examine, firing those customers that persisted in filing applications on "overly" complex inventions, and shifting much of the cost of patent examination to those applicants who refused to be fired.

These rules are summarized in Table 1. Each rule was characterized by hundreds of millions of dollars in annual paperwork burdens, which the USPTO ignored in making its preliminary determinations that they were not "economically significant," and almost certainly billions of dollars in economic effects, which the USPTO did not acknowledge, let alone estimate. For each rule, OMB rubber-stamped the USPTO's preliminary misclassification and declined to reclassify them even after having been presented proof of the error.

When public commenters presented alternative estimates of paperwork burden in the tens of billions of dollars of per year, the USPTO ignored these comments and, most astonishingly, blamed OMB for enabling its subterfuge. This is most transparent in the USPTO's response to a public commenter who objected to a proposed rule being designated as merely "significant" despite an estimated $264 million in annual paperwork burdens. It was the Patent Office's view that it had no obligation to correct its error as long as OMB did not order it to do so:

> [T]he Office of Information and Regulatory Affairs (OIRA) determines whether the Office's rules are ''significant'' and/or ''economically significant'' under Executive Order 12866. OIRA determined that these rules are ''significant,'' but not ''economically significant" … The Office presents each proposed rule to OIRA, which considers the economic significance of each rule individually.[67]

OMB may have a longstanding expectation that agencies would make preliminary designations in good faith based on the available evidence so that reclassification decisions by OMB are rarely necessary.[68] This expectation is not valid for the USPTO.

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[67] U.S. Patent and Trademark Office (2011), p. 72291.

[68] If taken literally, Executive Order 12866 § 6(a)(3)(A) gives OMB the infeasible task of discovering in just 10 days that a regulation preliminarily deemed "not significant" or "significant" by an agency is actually economically significant.

Table 1: Economically Significant Regulations Misclassified by the USPTO, 2007-2011

Year	Regulation (RIN)	USPTO/OMB Classification	Why Is It Economically Significant?
2006 2007	AB95 (P) AB95 (F)	Significant	Public comments show $ billions in paperwork burdens alone; no economic effects acknowledged
2006 2006 2007	AB93 (P) AB94 (P) AB93 & AB94 (F)	Significant	IRFA shows $ billions in costs to small entities; no economic effects acknowledged
2007	AC00 (P)	Not significant	Public comments show $ billions in paperwork burdens alone; no economic effects acknowledged
2007	AC12 (P)	Not significant	Public comments show economic effects well over $100 million per year; no economic effects acknowledged
2008	AC12 (F)	Significant	$240 million annual paperwork burden; no economic effects acknowledged
2009	AC37 (A)	Not classified	
2009	AC36 (F)	Significant	Public comments show economic effects well over $100 million per year; no economic effects acknowledged
2010	AC37 (RP)	Not classified	$264 million annual paperwork burden; no economic effects acknowledged
2010	AC37 (F)	Significant	
(A) Advance Notice; (P) Proposal; (RP) Re-proposal; (F) Final.			

E. The USPTO Does Not Comply with Executive Order 12866 Requirements to Estimate and Report Benefits and Costs for "Significant" Rules

The obligation to estimate and disclose estimates of costs, benefits, and other economic effects is not limited to economically significant regulations. For regulations that are merely "significant," agencies are required to provide to OMB

> [a]n assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner

> in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities…[69]

An agency's analytic responsibility thus extends to all draft regulations that OMB reviews. It is the intensity of this analysis that is supposed to become much greater for economically significant regulations. The eight proposed rules in this collection illustrate the USPTO's failure to comply with even this lighter analytic burden.

As I noted above, the USPTO provided no analysis whatsoever of costs, benefits, and other effects for any of the eight recently proposed regulatory actions implementing the AIA. Thus, even if the USPTO had properly classified each of these rules, it still failed to comply with analytic requirements that had been in place for more than 18 years for "significant" rules.

IV. To Establish a Semblance of Normalcy in Centralized Regulatory Review, OMB Must Subject the USPTO to Competent Oversight

There is a path forward to establish a semblance of normalcy in OMB review of draft rules submitted by the USPTO.

A. Immediately Reclassify the Eight Recently Proposed Rules as Economically Significant and Direct the USPTO to Perform a Comprehensive RIA in Accordance with Circular A-4

This is nothing more nor less than applying Executive Order 12866 as it should have been applied immediately after the AIA was enacted in September 2011. It is unfortunate that the USPTO now faces a tight deadline for the promulgation of these rules. Had the Office began an analytic effort in 2009 when it began lobbying Congress for the statutory changes that ultimately became the AIA, it would not be in this position today.

I realize that the USPTO's opposition to regulatory analysis may make it impossible to perform an RIA and meet the AIA's September 2012 deadlines. If in OMB's judgment a comprehensive RIA cannot be completed in time, Executive Order 12866 § 6(a)(3)(D) provides that agencies shall comply with these analytic requirements to the extent practicable even if compliance is delayed beyond the date of promulgation. Timely compliance to inform decision making is always best, but even late compliance provides an opportunity to perform the retrospective review (EO 13563 § 6) that will be needed to clean up the mess resulting from meeting the statutory deadline by promulgating regulations that are analytically indefensible and economically destructive.

[69] Executive Order 12866 § 6(a)(3)(B)(ii).

B. Designate All Future Patent Regulations Economically Significant by Default

As hard as it might be to designate the eight recently proposed rules as economically significant this late in the process, given the impending statutory deadline, it would be easy to designate all future patent regulations economically significant, thus establishing a presumptive requirement for the preparation of RIAs. A case can be made for downward reclassification of some rules as "significant" after the Office has performed, made public, and provided a meaningful opportunity for the public comment on credible analysis demonstrating that annual economic effects will not exceed $100 million. Another exception might be given to draft rules that are demonstrably deregulatory, for agencies should not be permitted to use the RIA requirement as a tool for avoiding regulatory reform. Still, as a general matter, the USPTO should bear the burden of proof that any draft rule it is considering is not economically significant.

C. Intensify OMB Review of USPTO Regulatory Actions

OMB is always short on staff to perform regulatory oversight, so more staff obviously would be helpful. In the short run, however, it makes sense to intensify OMB review by reallocating existing resources. It is no longer sufficient, if it ever was, for OMB to largely allow the USPTO to oversee itself. This model can only work in an agency that has an extraordinarily well-qualified economics staff, one that is fully independent of the agency's program officials and general counsel. The USPTO is not such an agency; its capacity and competence in economic analysis appears to be negligible.

Obviously, RIAs cannot inform regulatory decision making if they are never performed. When an agency evades the routine analytic requirements that Executive Order 12866 applies to economically significant regulations, it is simply impossible for the President to have any confidence that what the agency is doing has any merit whatsoever. Nor can the President credibly believe that the agency's regulatory actions reflect his priorities to the extent that Congress has delegated legislative decision making to the Executive. OMB is supposed to serve as an effective bulwark protecting against uninformed or mischievous agency rulemaking. It cannot fulfill this role if it chooses never to engage.

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