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**Sent:** Thursday, April 10, 2008 12:04 AM  
**To:** Markush-irfa.comments; Markush.Comments  
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**Subject:** USPTO Markush Rule - RIN 0651-AC00, and ICR's 0651-0031 and -0032 - take 2

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<<080409 Markush Rule NPRM and IRFA.pdf>>

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April 9, 2008

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cc: Carrol.Barnes@sba.gov, Office of Advocacy, U.S. Small Business Administration  
(Regulatory Flexibility Act issues discussed in § III at page 8 and § V at page 20)

cc: Robert.Clarke@uspto.gov, David\_Rostker@omb.eop.gov (Paperwork Reduction  
and Information Collection Requests 0651-0031 and -0032 discussed in § IV at  
page 14 and § V at page 20)

Re: RIN 0651-AC00, Examination of Patent Applications that Include Claims  
Containing Alternative Language, 72 Fed. Reg. 44992 (Aug 10, 2007) ("Markush  
Rule") and Initial Regulatory Flexibility Analysis 73 Fed.Reg. 12679 (March 10,  
2008) ("IRFA") and Paperwork ICR's 0651-0031 and -0032

Dear Ms. Fonda:

We appreciate the opportunity to comment on the proposed Markush Rules and  
the PTO's Initial Regulatory Flexibility Analysis (IRFA) and Paperwork Reduction Act  
Information Collection Request.

Our comments fall into four general categories:

1. Some of the proposed rules are contrary to law.
2. Others of the proposed rules are ambiguously drafted. This poor drafting will  
result in arbitrary enforcement, or renders the rules simply unintelligible, so  
that compliance is impossible.
3. The "analysis" in the Initial Regulatory Flexibility Analysis and the PTO's most  
recent Information Collection Request does not comply with the requirement  
to "describe the impact of the proposed rule on small entities," 5 U.S.C. § –  
the "analysis" ignores more of the "impact" than it describes.

4. The omissions and improbable estimates fall into a pattern of misleading statements to the Small Business Administration and the Office of Management and Budget that is so consistent as to raise questions of deliberate bad faith by the PTO.

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## **I. All PTO Rules are Fully Subject to the Regulatory Flexibility Act**

The IRFA states “The Office continues to believe that a regulatory flexibility analysis is not required for the [Markush Rule].” 73 Fed.Reg. 12680, col. 2. The PTO stated that the reason for non-coverage by the RegFlex Act was that the Markush Rule did not require notice and comment. 72 Fed.Reg. 44999 (Aug. 10, 2007). The PTO’s legal analysis is wrong.

35 U.S.C. § 2(b)(ii)(B) requires that all PTO rulemaking is subject to the notice-and-comment procedures of 5 U.S.C. § 553. *Tafas v. Dudas*, Memorandum Opinion on Cross-Motions for Summary Judgment at 13 (E.D. Va. Apr 1, 2008). Because all PTO

rulemakings are subject to notice-and-comment requirements, the PTO is required to fully comply with the Regulatory Flexibility Act for all rulemakings.

Notably, this includes the Markush Rule, the IDS Rule, and the Appeal Rule (and the Continuations and Claims Rules, if they are revived on appeal). All must be republished with Initial Regulatory Flexibility Analyses (or else credible Certifications) before they can go any further.

## **II. Several Provisions of the Markush Rule are Illegal or Poorly Drafted**

### **A. The Markush Rule Coins a *Sui Generis* Non-Statutory Definition for the Word “Invention,” Which Either Renders the Rules Unintelligible or Leads to Unintended Consequences**

The proposed rule text and preamble in the Notice of Proposed Rulemaking (NPRM) use the word “invention” to mean something other than “the scope of one claim.” Rather than use the long-established definition of the term “invention,” the NPRM uses the term in some loose sense, with no stated or inferable definition. This usage renders most of the NPRM simply unintelligible.

Since the late 19th Century, the term “invention” has been coextensive with the word “claim.” 35 U.S.C. § 112 ¶ 2 (claims “particularly point out and distinctly [claim] the subject matter which the applicant regards as his invention”) Throughout the patent law, the word “the invention” is constantly and consistently held to be coextensive with the scope of one claim, by definition.

By trying to split the two, and relying on some unstated informal definition for “invention,” the entire NPRM is unintelligible, and the text of the rules set no meaningful standards. For example, the NPRM proposes to amend 37 C.F.R. § 1.75(a) by adding the words “A claim must be limited to a single invention,” and to add § 1.140, “Two or more independent and distinct inventions may not be claimed in a single claim.” What can this sentence possibly mean? It represents such a departure from and is in such conflict with established meanings of words as to be meaningless, and can only serve to invite abuse by examiners. Is the sentence *intended* to be a meaningless tautology?

Does “A claim must be limited to a single invention” mean that no claim may have more than one dependent claim? That no claim may cover two disclosed embodiments?

It is truly impossible to comment with any precision on the NPRM, because established terms of art with precise definitions are used in meaninglessly-informal ways. The entire NPRM must be redrafted and repropose from scratch if the public is to have a meaningful opportunity for notice and comment.

**B. Rule 140(b), if Adopted at All, Should be Drafted to Clarify its Temporal Scope, and to Allow Applicants to Have the Options Necessary to Deal with Variability Among Examiners**

It is difficult to comment on proposed 37 C.F.R. § 1.140(b), because proposed 37 C.F.R. 140(a) is either illegal or so poorly drafted that the relationship to 140(b) is difficult to discern. However, in the event Rule 140(b) is adopted, it should be amended as follows:

~~(b) A The presentation of a claim that reads on multiple species using alternative language (§ 1.75(j)) may be accompanied by a statement explaining why the claim is limited to a single invention, or such a statement may be filed in traverse of a requirement for restriction. Such a statement shall be considered by the Office if filed by the applicant at the same time as the presentation of such a claim and may be considered by the Office if filed by the applicant after the presentation of such a claim but before the mailing date of any restriction requirement or action on the merits.~~

As drafted, Rule 140(b) requires applicants to preemptively guess how an examiner might view various technologies. Because the technological competence of examiners varies so widely, this is a practical impossibility. As drafted, Rule 140(b) gives examiners unrestrained ability to take unreasonable positions, and denies applicants the ability to rebut those unreasonable positions. If § 1.140(a) is adopted in any variant, the showing of § 1.140(b) should be a permitted basis of traverse at any time.

**C. The Proposed Amendment to 37 C.F.R. § 1.141(a) is Unreasonable**

The PTO proposes to amend 37 C.F.R. § 1.141(a) as follows:

~~(a) Two or more independent and distinct inventions should may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one~~

~~are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.~~

The elimination of “reasonable” options for applicants is unreasonable on its face.

Essentially all mechanical, electrical and computer independent claims cover multiple species. Removing the second sentence from Rule 141(a) will lead to unreasonable restrictions in these technologies.

#### **D. Rule 144 Should Not be Amended as Proposed**

Currently, a petition may traverse an improper restriction requirement any time up to a notice of allowance. The NPRM proposes to amend Rule 144 to require any petition from a restriction requirement to be filed within two months of the restriction requirement becoming final.

The proposed rule would operate to create double patenting in situations where the elected invention’s claims are amended so that they inhabit the territory of the non-elected claims. In such cases, the claims should be rejoined, but cannot be.

Second, restriction requirements are usually dashed off by the examiner without any genuine effort to understand the invention. The first thought is expended often much later, sometimes not until the second or third Office Action. Once the examiner actually engages with the claims, examiners in the mechanical, electrical, and computer fields writes something in a majority of those first solid Actions that constitute an admission that the restriction requirement was improper, typically (a) by searching subject matter in a class/subclass other than that designated in the original restriction requirement, or (b) by applying a single reference to claims that fell across the restriction groups, thereby negating “serious burden of search.” Applicants should not be foreclosed from raising the restriction issue after the examiner first engages with the application, because that is usually the point at which the examiner makes the record that permits a solid traverse.

#### **E. Rule 145 Is Illegally Overbroad Because it Purports to Authorize Divisions Beyond Those Authorized by Statute**

The PTO proposes to amend 37 C.F.R. § 1.145 as follows (this is apparently the first proposed amendment since at least 1959, 24 Fed. Reg. 10332):

§ 1.145 Subsequent presentation of claims for a different invention in an application filed under 35 U.S.C. 111(a).

If, after an Office action on an application, the applicant presents by amendment one or more claims directed to an invention distinct from and independent of the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181.

Read facially (and as applied by many examiners), Rule 145 operates when an applicant cancels all claims and replaces them with new claims, even if those new claims merely claim essentially the identical invention using different words, or that amend the scope of the claims by about the same amount as run-of-the-mill amendments.

35 U.S.C. § 121 only permits “divisional applications” (that is, a division into two or more daughters) when “two or more ... inventions are claimed” (present tense) in one application. Section 121 does not permit restriction between pending and cancelled claims. 37 C.F.R. § 1.145 should be amended to eliminate the ambiguity and clearly state the intent of the rule, without ambiguity that can be interpreted overbroadly:

§ 1.145 Subsequent addition of claims for a different invention in an application filed under 35 U.S.C. 111(a).

If, after an Office action on the merits, the applicant adds by amendment one or more claims directed to an invention distinct from and independent of the invention previously examined, and the previously-examined claims remain pending, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143, 1.144 and 1.181. Any requirement for restriction requires showings that the invention added by amendment is independent of and distinct from the examined invention, and creates serious burden of search.

The current unauthorized practice leads to significant satellite petition practice, and loss of patent term.

#### **F. Because of the PTO’s Confused and Undefined Usage of the Word “Invention,” Rule 146 as Drafted Operates Unreasonably**

The PTO proposes to amend 37 C.F.R. § 1.146 as follows:

§ 1.146 Requirement for an election of a single species in an application filed under 35 U.S.C. 111(a).

(a) If one or more claims are directed to a single invention but encompass multiple disclosed and patentably distinct species, regardless of whether the claim uses alternative language, the examiner may require the applicant to elect one species that is disclosed in the application as filed for initial search and examination.

Because the PTO relies on some undefined and counter-to-statute definition of the term “invention,” the scope of this rule is unclear. That lack of clarity will almost certainly lead to unreasonable application, especially in the mechanical, electrical, and computer arts. Essentially every claim in these areas is “directed to a single invention [that] encompass[es] multiple disclosed and patentably distinct species.” For example, almost every independent claim has several dependent claims directed to further limiting different parts of the parent claim, or adding limitations that have no direct correlate in the parent claim. As drafted, Rule 146 will effectively limit examination in most cases to one dependent claim. As drafted, Rule 146 is essentially a repeal of the PTO’s policy of “compact prosecution.”

**G. MPEP Chapter 800, particularly § 802.01, Misstates the Law, and Should be Corrected**

35 U.S.C. § 121 permits the PTO to restrict claims if the claims are “independent and distinct.” However, as a practical matter, the effect of Chapter 800 of the MPEP is to permit restriction if two inventions are independent or distinct. Chapter 800 should be redrafted to conform PTO policy to statute.

**III. The IRFA Omits Consideration of a Host of Required Issues, and Violates the Law by Breaching the PTO’s Regulations to Ensure its Own Rational Conduct**

The IRFA fails any test for being a “reasonable good faith effort” to address the needs of small entities. The IRFA ignores the vast majority of costs that will fall on small entities as a result of the Markush Rule, and the consideration that does exist is based on evidence that the PTO itself concedes to be mere “belief,” not objective. The IRFA violates both 5 U.S.C. § 603 and 607, and the PTO’s own Information Quality Guidelines.

Once an agency promulgates regulations for its own conduct, the agency is obligated to follow those regulations, and any agency action contrary to those regulations is void, illegal and of no effect. *Dodson v. Dep’t of the Army*, 988 F.2d 1199, 1204 (Fed. Cir. 1993). The IRFA violates a number of regulations that the PTO

voluntarily adopted for itself to follow. First among these are the PTO's own Information Quality Guidelines (PTO IQG's)<sup>1</sup>, issued pursuant to the Information Quality Act (IQA) (codified in notes to 44 U.S.C. § 3616, (agencies are required to "ensur[e] and maximiz[e] the "quality, objectivity, utility, and integrity of information (including statistical information) [they] disseminate..."). The PTO's own IQG's require "objectivity," and that information be "accurate, reliable, and unbiased," and "presented in an accurate, clear, complete, and unbiased manner" (PTO IQG, § IV(A)(6)). Data and analyses must be transparent and "reproducible" by competent third parties. The PTO commits itself to full public disclosure (PTO IQG, § IV(A)(7), underline added):

"Reproducibility" of these analytic results does include "especially rigorous robustness checks" and when asked the USPTO does provide disclosure of the data sources that have been used and the specific quantitative methods and assumptions (if any) that have been employed

Data, analyses, statistics, and similar "representation[s] of knowledge" that the PTO disseminates in rulemaking are covered by the PTO's IQG's ("information that ... forms any part of the support of the policies of the agency" are covered).

However, instead of relying on "objective" and "reproducible" information, throughout the IRFA, the PTO repeatedly states that it relies on nothing more than naked "belief," with no disclosed objective support. Much of what the PTO "believes" is not credible to anyone with any "professional background and experience" with the economic facts of patent life.

The applicable portions of the Regulatory Flexibility Act, 5 U.S.C. § 603 and 607, require an agency to "make a reasonable good faith effort" to address the costs that a regulation would impose on small entities. So much is omitted from the IRFA, and what is considered is considered on such a flimsy basis, as to raise genuine questions whether the PTO can meet even the most lenient standard of "reasonable good faith." *North Carolina Fisheries Ass'n v. Daley*, 27 F.Supp.2d 650, 659-60 (E.D.Va.1998) (an agency violated the RegFlex Act because its analysis "consciously ignored [its] own data and selected a flawed methodology").

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<sup>1</sup> <http://www.uspto.gov/web/offices/ac/ido/infoguideline.html>

### **A. The IRFA Hides Costs that Have Been Judicially Recognized**

The PTO failed to inform the Small Business Administration that an almost-identical Patent Office practice directed to Markush claims has been previously litigated, and the PTO lost. The NPRM and IRFA pointedly ignore the costs that the court noted in its decision:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification

*In re Weber*, 580 F.2d 455, 458, 198 USPQ 328, 331 (CCPA 1978) (emphasis in original). The NPRM pointedly ignores the restrictions (as opposed to election of species) that are to be generated under the proposed rules.

### **B. The PTO May Not Rely on “Belief” Without Objective Basis To Assert that Seven Divisional Applications Will Be Sufficient to Recover the Patent Rights that The PTO Proposes to Expropriate**

An Information Quality Guideline violation occurs at the bottom of 73 Fed.Reg. 12683, col. 1:

However, the Office believes that an applicant would need to file at most approximately seven divisional applications following an examiner’s restriction requirement, even if more were needed to seek patent protection for the full scope of the originally claimed inventions.<sup>4</sup>

<sup>4</sup> Applicants may file divisional applications sequentially to keep a case pending for the lifetime of a patent (twenty years) to take advantage of the time to determine whether any of their inventions turn out to have market value. The least-cost method of achieving this result would involve an applicant pursuing one divisional application at a time over a twenty-year period. Assuming the prosecution of each divisional application lasts three years, an applicant would be able to minimize the total cost by filing approximately seven divisional applications during this period.

This “analysis” is not only an illegal violation of the PTO’s IQG’s, it’s simply wrong, completely disconnected from the economic reality of the patent system. For example, where a number of different embodiments are commercially substitutable for each other

but meet the PTO's new, non-statutory test for division, the sequential divisional application strategy that the PTO suggests in footnote 4 is essentially a stripping of all value from a patent portfolio.

The following sentences explain the falsity of this sentence: it is not that applicants "need to file at most approximately seven divisional applications," but that applicants would be boxed in by other PTO rules and economic considerations to at most seven. Pinning the blame in the wrong place is not "objective" analysis that can survive RegFlex scrutiny.

### **C. The PTO's Analysis Omits the Overwhelming Majority of Costs**

The PTO misleads SBA by playing a shell game: the PTO explains that applicants can avoid the paperwork burden of rule implication A by following course B, and then fails to consider the costs of course B, and elsewhere explains that applicants can avoid the regulatory burden of B by following course A, and then fails to account for the costs of A. The PTO never grapples with the inconsistency in its explanations.

The IRFA states at 73 Fed.Reg. 12683, col. 1-2:

Therefore, while the cost impact of intra-claim restrictions could be as low as zero for applicants that elect not to maintain scope, it could range as high as the cost of seven divisional applications (present value of approximately \$42,000).

This statement is simply false on two separate grounds.

First, the statement can only be correct if the value of patents covering most-likely design-around products is zero. That is clearly false – patents **only** have value when they cover products that competitors would like to introduce.

Second, this sentence can only be true if the cost of a divisional is about \$6,000. But \$6,000 is approximately the cost of fees paid to the PTO (filing, issue, and maintenance fees), but excludes the host of other costs to be imposed on applicants. Apparently the PTO recognized RegFlex burdens only for **fees paid to the PTO**. The PTO excluded at least the following costs and burdens from its representation to the Small Business Administration:

- Attorney fees. Elsewhere in the IRFA, the PTO concedes that attorney fees for a divisional are typically over \$10,000. 73 Fed.Reg. at 12681 col. 3. Why were attorney fees not included here?

- Costs of analysis of information. 5 C.F.R. § 1320.3(b) requires that the PTO include the cost of **analyzing** any restriction requirement and **choosing** from among the groups. The PTO's Paperwork Reduction Act submissions simply ignore this cost.
- Additional bookkeeping costs. Dividing a patent into pieces creates many costs that are not reflected in the prosecution fees considered in the AIPLA survey – accounting, transfer costs, etc.
- The IRFA expressly refuses to consider loss of patent asset value, for example the value of patent protection lost when a claim must be divided and refiled at a filing date after the parent, therefore issuing long after the claims in the original application. This delay in issuance will, in many cases, permit competitors to enter the market with a knock-off disclosed in the patentee's own application but not yet pursued as a divisional, thereby depriving the inventor of any meaningful patent protection.
- The IRFA omits consideration of loss of patent term adjustment and extension for the claims of that must be moved to later-filed divisional applications.
- The value of patent protection abandoned because of divisionals not filed.
- The cost of litigating divided patents. Often, it is not clear precisely what an accused competitors' product is, and which particular prong of which patent claim might be infringed, only that there is infringement of the generic claim. The IRFA fails to consider the additional litigation cost that would be imposed by litigating **precisely** which division is infringed, as would be required by the proposed intra-claim division.
- The loss of value from “resulting fragmentary claims” that the court noted in *Weber*, 580 F.2d at 458, 198 USPQ at 331.

The PTO's “analysis” is contrary to the economic understanding of anyone with “professional background and experience in patent law.” 35 U.S.C. § 3(a). It is also contrary to the PTO's obligation to SBA under the Regulatory Flexibility Act to consider all paperwork and regulatory costs, that is, the cost of the alternative conduct required by the regulation and the costs of the opportunities foreclosed by the regulation.

This IRFA omits so many issues that no reasonable comment can be prepared. Without a meaningful opportunity to comment on an IRFA, the PTO will be unable to prepare a Final RegFlex Analysis that will survive judicial scrutiny. See *Southern Offshore Fishing Ass'n v. Daley*, 995 F.Supp. 1411, 1434-37 (M.D.Fla.1998) (agency “could not possibly have complied with [Final RegFlex Analysis requirement of] § 604 by summarizing and considering comments on an IRFA that [was] never prepared”). The PTO must disclose its analysis if the public is to have any reasonable opportunity as

contemplated by the RegFlex Act. The PTO should prepare another IRFA that makes a “reasonable good faith effort” to identify and quantify all costs associated with its rules, and publish it for comment. 5 U.S.C. § 603.

#### **D. The PTO Illegally Excluded the Cost of Abandoning Patent Protection Above Seven Divisionals**

The PTO then makes another statement with no objective support, and that is entirely contrary to the economics of patent protection:

However, the Office believes [ ] applications [in which seven divisionals will be filed to recover claim scope] are relatively few in number and the impact for most applicants will be far less.

What is the objective basis for this “belief?” And having conceded that there are some applications for which the full claim scope is economically necessary, and “more than 100 divisional applications” might be required, 73 Fed. Reg. at 12683 col. 1, where is the analysis of costs to those applicants? How can the PTO have met its self-imposed obligations to disseminate only “objective” “accurate” and “unbiased” information if it only considered best-case scenarios, and failed to quantify worst-case?

A RegFlex Analysis is fatally defective when only explains that some entities suffer only small consequences, but fails to analyze catastrophic effects on others. *Harlan Land Co. v. U.S. Dept. of Agriculture*, 186 F.Supp.2d 1076, 1097 (E.D. Cal. 2001) (vacating rule when the analysis considered only some small entities, and failed to consider the consequences on those most seriously affected).

#### **E. The IRFA Improperly “Fudges” the Numbers**

The PTO attempts to reduce recognition of some costs by reducing them to present value. This is impermissible. The Regulatory Flexibility Act recognizes costs in the year in which they are incurred, on an ongoing steady-state basis. Reducing some costs to present value as if accrual-basis accounting applied, in a cash-basis system like the RegFlex Act, is mixing apples and oranges.

The PTO applied a double standard: the PTO reduced **expenditures** to present value, but did not reduce the value of delayed patent **assets** to present value. The PTO

can't have it both ways, and cannot apply mutually-inconsistent accounting standards to revenue and expense recognition.

**F. The IRFA Breaches 5 U.S.C. § 603(b)(5) by Covering Up “Relevant Federal Rules Which May ... Conflict with the Proposed Rule”**

5 U.S.C. § 603(b)(5) requires an agency's IRFA to include “an identification, to the extent practicable, of all relevant Federal rules which may ... conflict with the proposed rule.”

As of March 10, 2008, the Continuations and Claims rules were still on the books, not having been invalidated by the Eastern District of Virginia in *Tafas v. Dudas*. The PTO misled the SBA by failing to disclose to the SBA the conflict between the Continuations/Claims rule. The PTO failed to inform SBA that the most natural-way of complying with the Markush rule, which would be to file a number of “voluntary divisional” applications. The PTO failed to inform SBA that the Continuations and Claims rules would make this practically impossible.

The undersigned attorney once represented a client in a negotiation in which the counterparty provided representations and analyses, and omitted information, of materiality similar to the defects in the IRFA. I recommend that the client end the negotiation immediately, because the counterparty was clearly either a liar or too incompetent to carry out the transaction that was being negotiated. Subsequent events proved the prediction to be correct.

**IV. The PTO Violated the Paperwork Reduction Act, Paperwork Reduction Regulations and Executive Order 12,866**

**A. The PTO Misrepresented E.O. 12,866 Burdens**

At 72 Fed.Reg. 44999, col. 2, the PTO makes representations to the Office of Information and Regulatory Affairs in OMB. These two assertions are off by billions of dollars.

*Executive Order 12866*: This rule making has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended

by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

The designation “not significant” is reserved for regulations that have only minor consequences and elicit little or no controversy, such as housekeeping actions, and matters for which the agency is willing and able to perform internal oversight equivalent to that of OMB. The PTO’s reiteration of the NPRM’s “determination” of “not significant,” on the same day that the IRFA admits to “significant” costs, demonstrates that the PTO has simply given up even the pretense of attempting truthful, objective analysis of its rules.

No possible analysis could get the cost of the Markush rule below \$100 million per year, the threshold for an “economically significant” rule that requires a full Regulatory Impact Analysis, except one that omitted most of the economic effect. The categories of costs that must be accounted for as “economic effect” under E.O. 12,866 are very broad, including all items listed in § III.C above. As noted above, the PTO simply neglected to account for required costs, and therefore the PTO’s E.O. 12,866 determination is arbitrary and capricious.

Extrapolating from the numbers given in the IRFA, it seems certain that a *minimum* of 100,000 additional applications will be required if applicants are to avoid regulatory burdens of lost patent protection.<sup>2</sup> The PTO admits that the costs for these applications are about \$16,000 each (\$6000 in filing, issue and maintenance fees, and \$10,000 in attorney fees). Thus, on the facts as the PTO admits them, the burdens of the Markush rule cognizable under E.O. 12,866 are **\$16 billion per year**. The Markush rule far exceeds the \$100 million threshold for an “economically significant” rule.

The PTO could pursue an alternative analysis, by assuming some smaller number of additional applications will be filed, **but only if** the PTO also accounts for the regulatory burdens of lost patent protection for divisionals either delayed or not filed.

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<sup>2</sup> Because the PTO refuses to acknowledge any regulatory burden of lost patent protection, E.O. 12866 requires that the PTO assume that applicants will fully exercise the alternatives available to avoid that loss. Agencies can’t have it both ways – they must either estimate and book the regulatory burden under E.O. 12,866, or must assume that all burden will shift to paperwork cost, and book that burden under the Paperwork Reduction Act.

Under that analysis, the paperwork costs might drop to “only” \$100 million per year – still above the threshold for an “economically significant” rule – but the PTO would then have to acknowledge **billions** of dollars per year of regulatory burden for lost patent protection.

It is difficult to see any way below the \$100 million threshold in any “reasonable good faith” effort to evaluate all burdens cognizable under E.O. 12,866. The PTO is required to withdraw the Markush Rule, and repromulgate it with a Regulatory Impact Analysis pursuant to OMB Circular A-4.<sup>3</sup> The formal structure of Circular A-4 may assist the PTO in making some honest attempt to evaluate the burdens (paperwork and regulatory) it proposes to impose.

### **B. The PTO Affirmatively Misrepresented Paperwork Reduction Act Consequences of the Rule**

5 C.F.R. § 1320.11 requires that all agencies, for all proposed rules, include a statement in the NPRM that all collections of information contained in the proposed rule have been submitted to OMB for review under the Paperwork Reduction Act. § 1320.11 requires that an agency comply with § 1320.8(d)(1), which requires an agency to “provide a 60-day notice in the Federal Register, and otherwise consult with members of the public.” All collections of information must be submitted to OMB with a review that includes “a specific, objectively supported estimate of the burden.” 5 C.F.R. § 1320.8(a)(4). An agency may not “conduct a collection of information” unless the agency has observed 5 C.F.R. § 1320.5(a), which requires a certification that the information “will have practical utility” (as that term is defined in § 1320.1), and is not “unnecessarily duplicative.”

The NPRM expressly states, 72 Fed.Reg. 44999, col. 2, that the PTO refuses to comply with these regulations:

*Paperwork Reduction Act:* This notice involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information involved in this notice have been reviewed and previously approved by OMB under OMB control numbers: 0651–0031, and 0651–

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<sup>3</sup> <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>

0032. The United States Patent and Trademark Office is not resubmitting the other information collections listed above to OMB for its review and approval because the changes in this notice do not affect the information collection requirements associated with the information collections under these OMB control numbers. The principal impacts of the changes in this proposed rule are to: (1) Expressly require that a claim be limited to a single invention; and (2) specify the conditions under which a claim that reads on multiple species by using alternative language to list species) will be treated as limited.

First, the entire thrust of the Markush Rule is to compel applicants to file more patent applications, at an **acknowledged** paperwork cost of about \$10,000 each, in an **acknowledged** minimum number of at least 13,000 per year – totaling about **\$130 million per year** – plus further **unacknowledged** burdens as listed in § III.C above. The PTO's refusal to account for the staggering Paperwork costs of the divisional applications required by the Markush Rule is beyond the pale. If the PTO's Paperwork Certification is anything other than an intentional misrepresentation in an effort to conceal the astronomical burdens of this rule from OMB review, the PTO should explain carefully.

Second, the paperwork burdens cannot possibly have been reviewed by OMB as required by regulation, let alone “approved.” The only candidate Information Collection Requests submitted to OMB for 0651-0031<sup>4</sup> and -0032<sup>5</sup> at anything close to the permissible time window are:

- 200707-0651-005<sup>6</sup> (submitted September 26, 2007). This ICR was sent to OMB after the notice-and-comment period for the Markush rule closed, and thus is too late to constitute a valid 60-day notice. Further, the PTO designated this as “Not associated with rulemaking,” thereby ensuring that OMB would not give this ICR review appropriate to a new rulemaking
- The Markush Rule published on August 10, 2007.
- 200706-0651-004<sup>7</sup> (submitted June 22, 2007) is the only ICR for either 0651-0031 or -0032 within the appropriate date window. This ICR was submitted by “Change Worksheet” without a Supporting Statement and without a Federal

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<sup>4</sup> <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0651-0031>

<sup>5</sup> <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0651-0032>

<sup>6</sup> [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200707-0651-005#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200707-0651-005#section0_anchor)

<sup>7</sup> [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200706-0651-004#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200706-0651-004#section0_anchor)

Register notice, and with no “specific, objectively supported estimate.” PTO characterized this ICR to OMB as “No material or nonsubstantive change to a currently approved collection” and “Not associated with rulemaking,” and thus avoided triggering OMB review. This ICR was disapproved by OMB. Thus, this ICR cannot possibly be the “review and previous approval by OMB” alluded to in the NPRM.

- 200703-0651-001<sup>8</sup> (submitted March 13, 2007) was also a mere “Change Worksheet” without either a Supporting Statement or a Federal Register Notice, and thus without a “specific, objectively supported estimate.” PTO characterized this ICR as “No material or nonsubstantive change to a currently approved collection” and “Not associated with rulemaking.” This ICR, nonetheless, included some significant changes in paperwork burden calculations, in violation of OMB guidance. This ICR was too early to constitute a valid 60-day notice, because the Markush Rule was not published to permit the public to comment until August 10, 2007.
- A number of earlier ICR’s are likewise too early to have constituted valid 60-day Notices. Strikingly, after June 2006, the PTO designated all its ICR submissions<sup>9</sup> for either 0651-0031 or -0032 as “Not associated with rulemaking,” thereby assuring that OMB would not review the ICR’s with the care appropriate to new rulemaking. If the PTO has not deliberately cloaked the Appeal Rule and Markush rules from OMB Paperwork review by misdesignating their nature and significance, the PTO should explain.

The number of errors, misstatements, mischaracterizations, and the like creates a strong inference that the PTO has structured its submissions to deliberately mislead regulatory oversight authorities and the public. Perhaps there is an innocent explanation; the PTO should provide it if it can.

The PTO should publish a detailed explanation of how these errors arose, should name the individuals that made the errors and those that signed off on them, and should publish guidelines to assure the public that this consistent pattern of error cannot recur.

The PTO should explain to Congress why the PTO has done such a poor job of complying with its Paperwork Reduction Act responsibilities, and should explain to

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<sup>8</sup> [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200703-0651-001#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200703-0651-001#section0_anchor)

<sup>9</sup> 200606-0651-001, [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200606-0651-001#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200606-0651-001#section0_anchor); 200603-0651-001, [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200603-0651-001#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200603-0651-001#section0_anchor), and 200512-0651-002, [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=200512-0651-002#section0\\_anchor](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200512-0651-002#section0_anchor)

Congress how it can exercise authority under proposed “Applicant Quality Submissions” any more responsibly than it has exercised authority under existing law.

**C. The PTO Has Not, and Apparently Cannot, Make a Certification under 5 C.F.R. § 1320.9**

The PTO has apparently never provided a § 1320.9 certification. It appears that no such certification could be made. For example, any certification that the Markush rule is not “unnecessarily duplicative” would seem difficult, in view of the requirement that all of the divisionals will necessarily include duplicative submissions.

**D. Required Remedial Action Before the Markush Rule May Proceed**

The defects in the Markush rule (and, in most cases, the Appeal Rule and IDS Rule, and any revival of the Continuations and Claims Rules as well) require the following remedial actions under Paperwork regulations (in addition to the actions noted above to cure RegFlex defects):

1. The PTO must provide a notice that complies in all respects with 5 C.F.R. § 1320.11, the rule covering paperwork created by proposed rules. The NPRM admits that paperwork burdens are created; an ICR must be filed and approved.
2. Even if the PTO regards the filing of divisionals as “not related to rulemaking,” the PTO must publish a 60-day notice under 5 C.F.R. § 1320.10 for nonregulatory paperwork burdens, and update its Supporting Statement
3. Whichever route the PTO chooses, all paperwork burden ICR’s must include “a specific, objectively supported estimate of the burden.” 5 C.F.R. § 1320.8(a)(4). The PTO’s past practice of simply providing summary estimates of number of affected applications, and estimated hours, with no disclosed basis for either, does not meet the PTO’s Information Quality Guidelines, and is thus illegal. A good example of objectively-supported, reproducible estimates appear in several of the paperwork submissions to OMB.<sup>10</sup> The burdens cannot possibly be zero, as the PTO’s paperwork discussion in the NPRM asserts, because the IFRA admits that they are non-zero.
4. The PTO must provide these estimates to OMB, and publish their availability in the Federal Register, in a manner that permits the public comment required by 5

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<sup>10</sup> See, for example, <http://www.reginfo.gov/public/do/DownloadDocument?documentID=57744&version=1>, <http://www.reginfo.gov/public/do/DownloadDocument?documentID=51962&version=1> and <http://www.reginfo.gov/public/do/DownloadDocument?documentID=57760&version=1>

C.F.R. § 1320.8(d). An APA Notice of Final Rulemaking will be insufficient response to public comments on paperwork, because no notice was provided of any opportunity to comment on paperwork burdens.

## **V. In Prior Rulemakings, the PTO Has Established of Pattern of Misrepresentations that is So Consistent and Pervasive as to Suggest Deliberate and Intentional Evasion of the Law**

The PTO has played fast and loose with the facts it has gave executive branch rulemaking oversight agencies.

### **A. The PTO has Repeatedly Attempted to Evade Oversight by the Office of Management and Budget by Misrepresenting the Economic Effect of its Rules and Mischaracterizing its Submissions to Oversight Agencies**

The PTO designated the “IDS Rule,” 71 Fed. Reg. 38808 (Jul 10, 2006), the “Appeal Rule,” 72 Fed. Reg. 41472 (Jul 30, 2007) and the “Markush Rule,” 72 Fed.Reg. 44992 (Aug. 10, 2007) as “not significant” for Executive order 12,866 purposes. This designation reflects the PTO’s certification to OMB that the costs of these rules are essentially zero, and that they raise no controversy.

The public comment letters show that these rules are at a minimum several tens of millions of dollars each.<sup>11</sup> A peer-reviewed, sworn affidavit estimated the cost of the IDS rule alone at over **\$7 billion** per year.<sup>12</sup> In a letter to the Office of Management and Budget, Dr. Richard Belzer describes the multiple people that had to sign off on the PTO’s various misstatements, opines that the PTO’s misdesignations and misestimates were “highly unlikely” to have been inadvertent, that the PTO’s “failure to disclose an unbiased cost estimate was knowingly misleading,”<sup>13</sup> and that “One can infer with reasonable certainty that USPTO deliberately evaded the requirements of Executive

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<sup>11</sup> <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/ab95/ids.htm>, <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/bpai/bpai1.html>, <http://www.uspto.gov/web/offices/pac/dapp/opla/comments/markush/markush.html>.

<sup>12</sup> <http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf>.

<sup>13</sup> <http://www.whitehouse.gov/omb/oira/0651/meetings/663.pdf> at page 5.

Order 12,866.”<sup>14</sup> Under Paperwork Reduction Act regulations, 5 C.F.R. § 1320.14(c)(1), the PTO was required to respond within 60 days if it disagreed with the analysis in this letter, or at least notify the authors of those comments if it wished to seek an extension.<sup>15</sup> The PTO has been silent for five months. Either the PTO acquiesces to the showings in this letter, or the PTO is breaking the law by failing to respond.

Robert Bahr of the PTO admitted to OMB that he had made a \$100 million “typographical error” to OMB and left it uncorrected for 15 months.<sup>16</sup> Again, the PTO offers no defense of its action, though it had ample opportunity to do so in the recent *Tafas v. Dudas* litigation.

Several of the briefs filed in the Virginia litigation described a number of other instances of game-playing and mischaracterizations that the PTO made to OMB and to the Small Business Administration relating to costs of its rules.<sup>17</sup> The PTO did not challenge that it made the complained-of statements to OMB and the Small Business Administration, or that the statements were materially misleading. Instead, the PTO simply acquiesced to these showings of error.

## **B. The PTO’s Previous RegFlex Certifications and Analyses have been Dramatically Flawed, Relying on Analyses that the Department of Justice Expressly Disclaimed**

In the PTO’s Initial Regulatory Flexibility Act Certification of No Substantial Impact for the “Examination of Claims” Rule (“Initial RegFlex Certification,” November 2005), the PTO exempted itself from doing a Regulatory Flexibility analysis, stating as follows:

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<sup>14</sup> <http://www.whitehouse.gov/omb/oir/0651/meetings/663.pdf> at page 5 of 11.

<sup>15</sup> The parties that filed comments have not received notice of the extension required by § 1320.14(c)(1). Therefore the PTO is in breach of this law as well.

<sup>16</sup> <http://docs.justia.com/cases/federal/district-courts/virginia/vaedce/1:2007cv00846/221151/178/1.html> ¶ 40.

<sup>17</sup> <http://docs.justia.com/cases/federal/district-courts/virginia/vaedce/1:2007cv00846/221151/173/>, <http://docs.justia.com/cases/federal/district-courts/virginia/vaedce/1:2007cv00846/221151/178/1.html>, and <http://docs.justia.com/cases/federal/district-courts/virginia/vaedce/1:2007cv00846/221151/268/>

The changes proposed in this notice will not affect a substantial number of small entities. [Based on the PTO's application tracking database,] only 1.2 percent of all nonprovisional applications and 1.3 percent of the small entity non provisional applications contain or were amended to contain more than ten independent claims. ... Therefore, the Office estimates that the proposed examination support document [ESD] requirement would not impact a substantial number of small entities.

Note that the 2005 version of the "Claims" rule triggered the ESD requirement based on the number of total claims, not the number of independent claims mentioned in the Initial RegFlex Certification. Proposed 37 C.F.R. § 1.75(b)(1)(ii), 71 Fed. Reg. 67, col. 3 (Jan. 3, 2006).

The PTO felt it important to explain to the *Tafas v. Dudas* court the crucial difference between "independent claims" and "total claims" as trigger points for various rules (PTO's Opposition to GSK, docket no. 247, at page 43), but did not feel it was important to explain this distinction to SBA. Nor does the Initial RegFlex Certification inform SBA that about 79% of applications (not 1.3%) have more than 10 total claims, and would therefore have been affected by the ESD rule.

One could easily infer that the PTO deliberately took advantage of the SBA's relative lack of familiarity with patent jargon to mislead SBA into believing that only 1.3% of small entities would be affected.

### **C. An Expert In the Field of Regulatory Oversight Opined in a Formal Written Declaration that the PTO has Knowingly Subverted Regulatory Oversight Procedure**

A sworn declaration by Dr. Richard Belzer, a former economist at OMB responsible for reviewing rulemaking submissions, opined on the PTO's compliance with OMB and SBA rulemaking procedure as follows (*italic in original, underline added*):

52. ... I have a *very high level of confidence approaching certainty* that the following inferences ... are true: (a) PTO knew or should have known that the regulatory actions listed in ¶ 31 were economically significant under EO 12,866 [rather than "significant" under the box that PTO checked]; (b) PTO knew or should have known that economically significant regulatory actions must be accompanied by a Regulatory Impact Analysis; ... (f) PTO knew or should have known that its certifications of no significant impact on substantial numbers of small entities were not analytically defensible; and (g) PTO withheld from OMB information crucial for estimating, within even an order of magnitude, the likely costs of the regulatory actions...

53. ... I have a *very high level of confidence* that the following inferences ... are true: ... (b) PTO knew or should have known that if the Office complied with the reproducibility requirement in [the PTO's own Information Quality Guidelines],

competent third parties were almost certain to try to show, and were more likely than not to succeed in showing, that the Office's estimates of programmatic effects were inaccurate and biased, and thus not substantively objective.

54. ... I have a *very high level of confidence* that the following inferences with respect to impacts on small entities are true: (a) PTO knew or should have known that any certification that the [rules] would not have a significant effect on a substantial number of small entities would be analytically invalid and unreliable; ... and (c) PTO knew or should have known that its characterization of impacts on small entities ... were nonsensical...

61. The most crucial elements of PTO's Reg Flex Analysis rest solely on the "beliefs" of PTO staff. ... it is significant that [the contractor who prepared the PTO's Reg Flex certification analysis] declined to take responsibility for, or attempt to analytically support, PTO's "belief."

## VI. Alternatives

35 U.S.C. § 41(d)(2) states that "The Director shall establish fees for all other processing, services, or materials relating to patents ... to recover the estimated average cost to the Office." Executive Order 12,866<sup>18</sup> § 1(b)(3) requires that the PTO consider "providing economic incentives to encourage the desired behavior." At 73 Fed.Reg. 12683, col. 2-3, the PTO states that it refuses to even consider following the law.

The reasons that the PTO has lost the ability to build consensus, or even to follow the law, relates to past conduct by senior PTO management.

In April 2002 that the Office proposed an exponentially-escalating fee structure that had nothing to do with average cost, but was instead expressly stated to be a punitive measure directed to "modifying applicant behavior."<sup>19</sup> The patent community saw this as an expression of hostility by the PTO to the characteristics that make strong patents.

In the 2006-07 rulemakings, the PTO illegally hid all of its underlying data, information, computer analyses, etc. from the public, from OMB, and from SBA.<sup>20</sup> The

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<sup>18</sup> [http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866\\_amended\\_01-2007.pdf](http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf)

<sup>19</sup> <http://web.archive.org/web/20021005230103/http://www.uspto.gov/web/offices/com/strat2001/faq.htm#q53>

<sup>20</sup> <http://docs.justia.com/cases/federal/district-courts/virginia/vaedce/1:2007cv00846/221151/173/> at pages 5-10.

public presentations by senior PTO officials confirmed only that the PTO had no understanding of the patent system.<sup>21</sup> When the PTO was asked by FOIA to justify its statements, the PTO stonewalled.<sup>22</sup> When the PTO produced its documents in the *Tafas v. Dudas* litigation, the absence of any consideration by the PTO of any factor economically-relevant to the public became starkly clear by the absolute absence of any analysis of economic effects on applicants in the administrative record.

Senior PTO management – Mr. Dudas, Ms. Peterlin, Mr. Doll, Mr. Love, Mr. Toupin, Mr. Bahr – is no longer trusted by the PTO’s customer base. They have convinced the patent bar that they have no understanding of the patent system, are unwilling or unable to look at any effect that would occur outside the PTO’s four walls, are unwilling to allow themselves to learn, and have too little respect for the rule of law to be able to avoid the legal fiasco that led to the PTO’s defeat (and likely payment of non-capped Equal Access to Justice Act fees to plaintiff Tafas) in *Tafas v. Dudas*. The patent community has become convinced through the public statements of these particular individuals that they have too little understanding of the role patents play in

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<sup>21</sup> For example, in a talk to a room of about 100 patent attorneys in Hot Spring, Virginia on October 22, 2007, James Toupin answered a question from the audience relating to inequitable conduct and the PTO’s proposed “Examination Support Document” rule. My notes, which I took as close to verbatim as possible within seconds of the discussion, reflects that the questioner noted that “all attorneys agree” that the inequitable conduct risks are so high as to make ESD’s “unusable.” My Toupin conceded, “I understand they all agree. I disagree.” (exact quote). But Mr. Toupin did not explain any basis. Even Mr. Toupin’s former chief assistant, John Whealn, agreed that ESD’s created an unacceptable inequitable conduct risk. <http://realserver.law.duke.edu/ramgen/spring06/students/02172006a.rm>, at time mark 1:02:58. The public record does not reveal that Mr. Toupin has any practical experience with the law of inequitable conduct on which he could base an informed opinion. Good lawyers are careful not to elevate personal opinion above that of “all attorneys” who “agree” with each other, unless they have given very careful consideration to the issue, and can fully explain the position of disagreement.

<sup>22</sup> See, e.g. the PTO’s assertion that would make not make any information “available for public inspection” [http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp\\_continuation/alderucci.pdf](http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/alderucci.pdf), or that the PTO’s entire file for the Continuations, Claims and IDS rules amounted to a total of 114 pages of summary information, <http://www.whitehouse.gov/omb/oira/0651/meetings/619-3.pdf> pages 167-282, thereby confessing that the PTO had never taken a careful look at any relevant facts and concealing the several thousand pages that the PTO later produced in *Tafas v. Dudas*.

the real economic world of business to be able to understand the consequences of their proposed rules.

The IRFA is correct – present senior PTO management is probably unable to gain consensus for economically rational pricing, because the patent community does not trust present management to exercise sound judgment. The solution is PTO management that can demonstrate sufficient understanding of the issues to earn the trust of stakeholders, not economically-irrational rulemaking.

## **VII. Conclusion**

The PTO's current regulatory machinery is so badly broken, and in such open rebellion against good government regulatory oversight, that it should simply be closed down. Until a new Director and Deputy Director with "background and experience in patent and trademark law" are appointed, and new people with some knowledge of patent law and economics – and at least a minimal respect for the rule of law – can be hired to fill its Commissioner, Deputy Commissioner and General Counsel level positions, the PTO simply cannot act for the public good in its rulemaking.

The Markush Rule violates the Patent Act. The PTO's rulemaking procedure for the Continuances, Claims, IDS, Appeal and Markush Rules violated the Regulatory Flexibility Act, the Paperwork Reduction Act, 5 C.F.R. § 1320.01 *et seq.*, and Executive Order 12,866. The IDS Rule, the Markush Rule, and the Appeal Rule should be withdrawn. The PTO should issue proper 60-day notices under 5 C.F.R. § 1310.8(d)(2)(i), and republish any rules it wishes to promulgate with proper Initial Regulatory Flexibility Analyses and Paperwork Reduction Act disclosures under 5 C.F.R. § 1320.8, 9 and 11. The PTO must conduct proper Regulatory Flexibility Analyses under E.O. 12,866 and OMB Circular A-4. All of these rules must be

reproposed for a new round of Notice and Comment. Further action by the PTO is illegal until it has made some good faith attempt to comply with the law.

Sincerely,

/s/ David E. Boundy

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