David E. Boundy and Dean P. Alderucci
Cantor Fitzgerald, L.P.
499 Park Ave.
New York, NY 10022

October 11, 2007

By Email BPAI.Rules@uspto.gov
Mail Stop Interference
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

cc: Robert.Clarke@uspto.gov (information Collections discussed in § VII.F)

cc: Magdalen.Greenlief@uspto.gov (Attachments E and F)

Re: RIN 0651-AC12, Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals, 72 Fed. Reg. 41472 (Jul 30, 2007) ("Appeal Rules")

Dear Judges McKelvey and MacDonald:

We appreciate the opportunity to comment on the proposed Appeal Rules. As a preliminary matter, we agree that the problems sought to be addressed by the proposed Appeal Rules are very important – reducing backlogs in the appeal process and improving quality of the examination. However, we have concerns whether the proposed Appeal Rules address the underlying causes of these problems and whether certain of the proposed Appeal Rules, as presently written, will unfairly damage applicants' ability to obtain prompt, fair and accurate consideration of the merits of their inventions.

Our comments fall into four general categories:

1. Some of the proposed Appeal Rules place disproportionate burdens on appellants that undermine the statutory right to have an efficient, full and fair adjudication of patentability.

2. The Rules repeatedly set out a double standard, in which examiners are permitted to raise new grounds and adduce new evidence, while appellants' rights to fully and fairly reply are cut off.
3. Some of the proposed Appeal Rules improperly shift the burden of proof or are otherwise "substantive," and therefore exceed the authority of the Office. There are a number of other failures to comply with various rulemaking statutes and regulations.
4. The Proposed Appeal Rules introduce confusing and unnecessary new terminology for well established legal terms of art.

Table of Contents

I. Established Term of Art “New Ground of Rejection” Should Not be Changed to “New Rejection”

The proposed Appeal Rules introduce the new term “new rejection” (see, *e.g.*, Proposed Rule 41.39(b), 41.50(d), etc.) to replace the established term “new ground of rejection.” The prior terminology is extensively discussed in court and Board precedent, and should be fairly well understood.

We are concerned that this change in terminology could suggest a “new rejection” is something different than the established term “new ground of rejection.” In a telephone call on September 14, Judge MacDonald confirmed that the change of vocabulary from “new ground of rejection” to “new rejection” was not intended to be a change in the legal standard, only a change of name. We urge that terms of art not be disrupted and that the proposed Appeal Rules be amended to conform to the established terminology.

Importantly, in a world of electronic legal research, changes of terminology create real problems. Further, this particular choice of new vocabulary interacts with the recent rework of the Board’s web pages. The anemic search capability provided to search the newly-configured web site of Board decisions, combined with a web page organization that makes the Board’s decisions invisible to commercial internet search engines, would make it all but impossible to search for the new term “new rejection” without getting lots of false hits.

We suggest that a “Restatement” of the definition of “new ground of rejection” should be added to the MPEP. See Attachment F.

II. The Proposed Page Limit Is One-Sided And Does Not Account Appropriately for Circumstances Created by the PTO

The PTO is in roughly the same position in the legal system as the International Trade Commission, and therefore should have roughly the same page limit as the ITC: none. If the Board believes a page limit is appropriate (which we think it is not), then the Board should adopt the Federal Circuit's far larger limit of 14,000 words, and a more-liberal procedure for expansion, to match examiner's unbounded ability to generate large Office Actions.

A. A Combination of Multiple Limits Imposed Solely on Appellants Is a "Substantive" Reformulation of a Proceeding

When combined, the various limits imposed in the propped Appeal Rule accumulate to a substantive denial of an applicant's right to a fair and efficient appellate review. Increased fonts, decreased page limits, added material that must be included, no limits on the amount of material that an Examiner can present, and a draconian remedy for failing to address every point raised by an Examiner – all make one question the motivation for these proposed changes. At some point, a collection of "procedural" limits becomes so stringent that they amount to a "substantive" limit on the ability to prosecute an application. *In re Fibreboard Corp.*, 893 F.2d 706, 711 (5th Cir. 1990) considered a collection of rules that, taken individually, were "procedural" in character, but that taken in aggregate acquired a "substantive" character, and were therefore illegal:

> There is a point, however, where cumulative changes in procedure work a change in the very character of a trial. Significantly, changes in "procedure" involving the mode of proof may alter the liability of the defendants in fundamental ways. We do not suggest that procedure becomes substance whenever outcomes are changed. Rather, we suggest that changes in substantive duty can come dressed as a change in procedure.

Here, the combination of (1) the new limits placed on continuations and requests for continued examination, (2) the closing of the applicant's half of the record on appeal while (3) the examiner's remains wide open, (4) the requirements for more

background discussion and (5) discussion of issues that have nothing to do with any issue on appeal, with (6) a *very* short page limit, cumulatively "work a change" that together become "substantive" and therefore outside the PTO's statutory authority. Cumulatively, these changes so deprive applicants of a meaningful right to be heard at ***any*** time during §§ 131, 132 or 134 proceedings as to deprive them of due process.[1]

When these constraints are juxtaposed against the Office's refusal to enforce any analogous procedural limits on examiners, or any limit on examiner's papers or ability to introduce new evidence *at any time*, it is hard to escape a conclusion that the page limit is arbitrary and capricious under 5 U.S.C. § 706.

B. The 25-page, 14-point, Double-space Limit Compromises Due Process

While we understand that the Board does not desire to read endless arguments and thus would desire some form of page limits, the proposed Appeal Rules are lopsided. They impose strict page limits on applicants but not on Examiners. At the same time, they require pages of new discussion that is not material to the issues on appeal, and set harsh penalties for not addressing every argument raised by an Examiner.

If any limit is adopted, which we oppose, we offer an alternative to proposed Bd. R. 41.37(v)(5). A word limit, like the Federal Circuit's, rather than a page limit, will assist appellants in providing briefs that are genuinely helpful to the Board. Applicants should be encouraged to include helpful drawings in the bodies of their

---

[1] A patent is "property," 35 U.S.C. § 282, and an applicant is "entitled" to it, 35 U.S.C. § 102, *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) ("If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent") until the Office meets a *prima facie* burden to show grounds to withhold grant. Therefore patent applications are within Constitutional Due Process. *See Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972).

briefs, not discouraged. The limit should be calibrated to the size of the examiner's action. A simple reminder of the importance of brevity and focus (as proposed in the following markup) will achieve the Board's intended result, without raising due process concerns.

> (5) *Length of appeal brief*. An appeal brief may not exceed 14,000 words, or 1.5 times the number of words of the examiner's Office Action from which appeal is taken (including any previous action incorporated by reference), whichever is greater ~~25 pages~~, excluding any statement of the real party in interest, statement of related cases, table of contents, table of authorities, signature block, and appendix. An appeal brief may not incorporate another paper by reference. Appellants are encouraged to include drawings in the body of the brief at the point at which they will be most useful to the Board. Appellants are reminded that a brief is only persuasive if it is read, and longer or repetitive briefs inevitably receive less careful reading. A request to exceed the page limit shall be made by petition under § 41.3 filed no later than concurrently with filing with the Appeal Brief ~~filed at least ten calendar days prior to the date the appeal brief is due~~.

The requirement for 14-point type, double-spaced cuts the effective space available almost in half compared with the conventional 12-point formatting used in the Board's decisions. (As an experiment, we reformatted this document to 14-point, double, and it came within one page of doubling in size.) Using the formatting required and used by most other papers to and from the PTO, the proposed 25-page limit corresponds to just over 13 pages, barely the size of most Board opinions. Further, Board opinions do not include sections analogous to those proposed in Proposed Bd. R. 41.37(k), (l), (m), (n), and several requirements of (o) – thus the practical limit for discussion in an Appeal Brief would be shorter than the typical decision.

As a practical matter, these new requirements will dramatically limit the arguments that an appellant will be allowed to pursue, and the ability of an appellant to teach the Board what it needs to know about the technology at issue. We sampled the appeal briefs in the most-recent 20 Board decisions, and found that at least 2/3 would exceed this limit when reformatted – and those were briefs filed under the current rules, without the new requirements imposed in this round of rulemaking, and

without the refining of issues that occurs under current continuation practice. It is almost certain that 25 pages, double-spaced, 14-point, with new added requirements, will routinely be inadequate, and will result in a substantial destruction of patent rights to which applicants are legally "entitled" (35 U.S.C. § 102).

Further, the proposed limit is well below that of any court or comparable agency:

- The International Trade Commission frequently receives briefs of well over 100 pages, even on appeal to the full Commission from an ALJ. Agency briefs are necessarily more detailed than court briefs, because agencies typically decide the entire case in one round, where courts almost always decide in several. The standards for court/agency review are different than the standards for court/court review, and require that issues be fully briefed to the agency if there is to be a meaningful decision by the agency that can be reviewed by a court. Because of the relationship of courts to agencies, it is crucial that an applicant be able to present every relevant issue, and receive a decision from, the agency's highest tribunal, if the guarantees and judicial review provisions of the Administrative Procedure Act are to mean anything.
- The proposed 25-page, 14-point, double spaced limit is less than 30% of the 14,000 word limit at the Federal Circuit.
- The Eastern District of Virginia Local Rules specify a page limit of 30 pages, 12-point – which is well more than double the proposed limit. In addition, in Virginia district court, a case is frequently decided in several stages (Rule 12 motions on the pleadings, several stages of summary judgment, etc.), and even at the same stage, issues can be "carved up" into parallel separately-briefed portions, so that the number of pages available is far larger.

Because there is no evidence from the preamble or in the rulemaking file on the PTO's web site suggesting that this limit was selected thoughtfully after any plausible analysis of real-world data, it appears on its face to be arbitrary and capricious.

C. If any Page Limit is Adopted, The Enlargement Rule Should be Liberalized

The 10-day petition for expansion of the page limit of Proposed Bd. Rule 41.38(v)(5) is also unduly limiting. Briefs often do not gel until late in the process. With such tight limits, Applicants will be forced to routinely file prophylactic petitions

for extra pages, before they know or understand how many pages are really needed. This extra burden adds to the costs and burdens of the appeal process. Further, there is no meaningful remedy if the petition is denied: if appellants are forced to waive an issue at the Board of Appeals, there is no way to revive it later when the Federal Circuit provides a larger page limit.

Standard practice in most district courts for, *e.g.*, a supplemental complaint, is to file the proposed paper with the motion for leave to file it. If any page limits are adopted, then an analogous enlargement practice should be adopted. If the rule provides that the petition is to be filed with the brief itself, the APJ deciding the petition will have all the facts necessary to make an informed determination of whether the brief is reasonably focused, or a waste of printer toner that should be ordered shortened.

D. The Page Limit so Inadequately Supported as to be Illegal

There is essentially no rationale given for setting the page limit at 25 pages, 14-point, double spaced. With no rationale, the limit is arbitrary and unsupported by substantial evidence. The Notice of Proposed Rulemaking is also illegal for failing to consider the affect on those parties who would be affected. *Levine v. Apker*, 455 F.3d 71, 85-86 (2d Cir. 2006) (agency may not set an arbitrary numerical cut-off without considering all the factors, in this case, those included in § 2(b)(2)(F), which we discuss next).

III. The Proposed Appendices Impose Burdens Far Out of Proportion to their Usefulness to the Board

The Office's rulemaking authority is bounded by concerns of "cost effectiveness." 35 U.S.C. § 2(b)(2)(F). Further, Executive Order 12,866 says:

> Each agency shall tailor its regulations and guidance documents to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities),

> consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

Strikingly, this Notice of Proposed Rulemaking does not even hint that any study or evaluation was performed of costs or burdens, let alone the nature or conclusions of that study or analysis. "Cumulative regulations," in particular the Continuations Rule, are totally ignored. It appears that the Office is, once again, conducting its rulemaking proceedings based on failure to inform itself of the facts. Rulemaking with the inadequate factual consideration of costs that we discuss in this § III is illegal, for legal reasons we discuss in §§ VII.C and VII.F.

A. The Proposed Claim Support Section and Drawing Analysis Section Should Be Calibrated to the Issues of the Appeal

The proposed Appeal Rules requires that every appeal have a "claims analysis section" and "drawing analysis section" analyzing every limitation of every separately-argued claim, even for absolutely routine and undisputed limitations. (See Bd. R. 41.37(q) and (r)). While we understand and appreciate that there can be times that some such information can be useful to the Board, in turn the Board should understand that such a section places a burden on applicants that can significantly increase the costs of an appeal; we estimate these added costs as being in the range of $1000-$2000 per appeal for these two sections alone (based on an attorney average hourly rate of $335 per hour, and three to six hours of analysis). The Board is required to frame its rules to be "cost effective," 35 U.S.C. § 2 U.S.C. § 2(b)(2)(F), and cannot simply dismiss those costs.

It would be more appropriate to limit this burden to situations where the analyses relate to the dispute that is on appeal. Thus, the "claims analysis section" and "drawing analysis section" should be reframed into an alternative that is less burdensome for appellants, and more useful to the Board. For example, the following paragraph could be added to Bd. R. 41.37(o)

> (new) If the appeal turns on a claim limitation that is not a familiar and established term of art, appellants are encouraged to paste the relevant figures,

> and block quote the relevant portions of the specification, at the beginning of the argument relating to the particular issue. This exposition will not be counted against the word limit of Bd R. 41.37(v)(5).

This material is far more useful if it is placed close to the argument, and appellants should be given every incentive to do so without penalty.

While we can understand the usefulness of such analysis in some circumstances, we must observe that the Board regularly notes that it is not permitted to rely on the specification, drawings or file history in "construing claimed terminology and limitations when applying the prior art." *Ex Parte American Academy Of Science Tech Center*, 1999 WL 1736095 at *4 (BPAI Aug. 24, 1998) (holding that an agreement on claim scope memorialized in the file history could not be honored), *aff'd* 367 F.3d 1359, 70 USPQ2d 1827 (Fed. Cir. 2004). The Board is required to apply the "broadest reasonable interpretation consistent with the specification." If the appellant desires examination at the full breadth of the term, there is no reason to require identification of information that cannot be relevant to the Board's decision. The "claim support" and "drawing analysis" sections seem almost calculated to lead the Board into error.

The fact that the rule proposes to place the "claims support" and "drawing analysis" in a special section far away from the argument suggests that the Board recognizes that most of the information that is requested will never be useful. A more compact, focused alternative should be used instead.

B. The Pagination Requirements as Framed Are <u>Immensely</u> Burdensome

The appendix and pagination requirements of Proposed Bd. R. 41.37(v)(1) are far more burdensome than the Board recognizes. For example, they are far more burdensome than the corresponding requirements for briefs to the Federal Circuit, because they leave no room for the various techniques that are expressly encouraged in the Federal Circuit's local rules to make producing an appendix a tractable process. For example, the rule requires page numbers to be "consecutive,"

with the brief starting at 1 – which means that the brief has to be completed roughly two weeks before it is due, so that the appendix can be assembled and page numbered starting at the last page number of the brief, and then the appendix page numbers substituted back into the brief. If the attorney has a change of mind, or a new Federal Circuit case comes out, or substituting appendix page numbers into the brief alters the pagination, then the whole process has to be started over again from scratch.

The purely ministerial tasks of assembling and page-numbering the appendix, and then substituting appendix page numbers into the brief cannot be done automatically, and often takes full *days* of attorney and paralegal time. It often involves lining up a vendor to image and page number the pages. Merely the coordination of various people to prepare a Federal Circuit appeal appendix is at least an hour, and sometimes several hours, of attorney time – plus more time to assemble the work for handoff, and reviewing what comes back. Six hours is a *very* conservative estimate for the total burden imposed by the page numbering requirements of the appendix. For the 18,500 appeal briefs filed, at a blended attorney/paralegal rate of $250/hr, this appendix alone imposes over $ 28 million in incremental costs over current rule.

As we note in § VII.F below, the demand that applicants resubmit information that the PTO already has violates the Paperwork Reduction Act.

Current rule provides for citation into the prosecution history record, and discourages resubmission. The Board should specify a preferred citation form for citing prosecution history papers, and leave it at that.

C. Is a Table of Authorities Sufficiently Useful to Warrant the Burden?

A “Table of Authorities” is not easy to generate. Before adding this requirement, the Office should experiment with the “Table of Authorities” tool in Microsoft Word. It requires a great deal of manual intervention to get any meaningful,

minimally-correct result. A "Table of Authorities" never comes out right the first try, has to be redone several times as the brief nears completion. It has to be reformatted and reordered several times, etc. In total, a Table of Authorities takes a bare minimum of 2 or 3 hours for a well-behaved 20-page brief, and almost always considerably more.

A Table of Authorities will be entirely ignored in the 2/3 of appeals that are decided in the Technology Centers before reaching the Board – the effort will be totally wasted.

As a practical matter, appeals to appellate courts are overwhelmingly directed to close issues of law. A Table of Authorities is genuinely useful in appellate courts. However, appeals to the Board rarely turn on fine points of law. A Table of Authorities is much less likely to have use to the Board commensurate with its costs to appellants. Executive Order 12,866 would be violated by this requirement.

D. The Cost Estimate Statements are Not Adequately Supported, and Far More Costly than the Board Acknowledges

The one sentence that considers burdens on appellants, "Any additional time burden … is believed to be *de minimus* [sic] in comparison to the reduction in pendency…" simply ignores the fact that "pendency" is already compensated for by patent term adjustments of 35 U.S.C. § 154(b).

Strikingly, this rulemaking states that costs on applicants are very small, but never even hints that any study or evaluation was done to establish any basis for that statement. 72 Fed. Reg. 41484. col. 1 (characterizing burdens on applicants as "*de minimus*" [sic] only when <u>compared</u> to reduction in pendency). The costs of pendency are near zero for most applicants, because of patent term adjustment under § 154(b). Is the Board contending that the burdens are essentially zero? As we discussed in this § III, the Office's cost assertions are arbitrary, capricious, and unsupported by substantial evidence, and just plain wrong.

IV. Evidence Submitted After Notice of Appeal

Proposed Bd. R. 41.33(a) and (d) should be amended as follows:

> (a) *Amendment after notice of appeal and prior to appeal brief*. An amendment filed after the date a notice of appeal is filed and prior to the date an appeal brief is filed may be admitted (i) as provided in § 1.116 of this title, or (ii) if it is directed to a new ground of rejection or new points of argument raised in the final Office Action or in any post-final Office paper.
>
> (d) *Evidence after notice of appeal and prior to appeal brief*. Evidence filed after the date a notice of appeal is filed and prior to the date an appeal brief is filed may be admitted if (i) it is directed to a new ground of rejection or new points of argument raised in the final Office Action or in any post-final Office paper, (ii) the evidence recently became available, or (iii) the examiner determines that the evidence overcomes some or all rejections under appeal and appellant shows good cause why the evidence was not earlier presented.

New grounds of rejection are frequently raised in final Office Actions and Examiner's Answers. Unfortunately, in our experience, those who decide petitions have openly refused to even inform themselves of what the law of "premature final rejection" is, let alone apply it:

- Attachment B (T.C. Director states that he refuses to consider agency or court precedent on definition of "new ground of rejection," and insists instead that he will make up his own definition);
- Decisions on Petition in 09/385,394 of summer-fall 2003 and fall 2005 (refusing to acknowledge the legal definition of "new ground of rejection" or the full scope of Rule 116).

Applicants are frequently faced with multiple procedural irregularities by the examining operation, which prevent development of issues sufficiently to determine what evidence should be introduced, let alone actually introduce it at the time specified in Bd. R. 41.33(a) and (d). Even the Board has recognized this shortcoming.[2] These types of problems are further exacerbated by the new Continuations Rule promulgated on August 21, 2007, which proposed that appeal be the cure-all for "stubborn examiners" and further reduced applicants' ability to obtain

[2] See cases cited in footnote 34.

complete examination before appeal. Either the examination process must be reformed to provide procedural regularity and predictability, or the appeal process must retain flexibility for applicants to deal with all examiner errors.

The rule preamble comments as follows:

> The Office has found that too often an applicant or a patent owner belatedly presents evidence as an afterthought and that the evidence was, or should have been, readily available. Late presentation of evidence is not consistent with efficient administration of the appeal process.

While we understand and commiserate with the Board that this situation no doubt exists, unfortunately it cannot be solved in the manner proposed in the Appeal Rules.

First, a "Board-centric" optimization of "the appeal process" is not permissible for an agency, let alone one part of an agency. The "cost effectiveness" requirement of 35 U.S.C. § 2(b)(2)(F) requires the PTO to consider all costs and the efficiency of the entire examination/prosecution process, including costs on both the agency and on the public. Introduction of evidence after a Notice of Appeal will often be the most efficient way for the entire process to proceed, especially under the new Continuations Rule regime where the use of continuations to introduce new evidence is narrowly constrained.

Second, if "evidence as an afterthought" from an appellant is "inconsistent with efficient administration," then so are new evidence and "new grounds of rejection" from an examiner. It would be arbitrary and capricious for the Office to treat the two differently.

If examiners may raise new grounds and new evidence in Examiner's Answers, then appellants must be given reasonably symmetric opportunities. If appeal is on a closed record, then both halves of the record must be treated equally.

V. Examiner's Answer

A. Proposed Bd. R. 41.39(b) and 41.50(a), "New Grounds" in an Examiner's Answer

Proposed Bd. R. 41.39(b) reads as follows:

> (b) *New rejection in examiner's answer*. An examiner's answer may include a new rejection.

Rule 41.50(a) is also proposed for rewriting, in a very subtle way that is not discussed in the preamble to the Notice of Proposed Rulemaking, to give the Board the power to affirm or reverse *Examiner's Answers*, not the "decisions" of the examiner from which appeal was taken.

At the very least, appellants should be permitted to regroup claims and separately argue new claims, and should be permitted to introduce new affidavit evidence in response to new grounds of rejection, and new grounds introduced in an Examiner's Answer should trigger the full rights of Rule 41.30(d) if affirmed.

The Office lacks the authority to grant unbounded "new grounds" authority to an examiner. 35 U.S.C.§ 134(a) only grants the Board jurisdiction to hear appeals from the "decision of the primary examiner," not appeal from a brief. The administrative law has long made clear that agencies may not introduce new explanations in appellate briefs to courts after the decision, *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 168-69 (1962) ("*post hoc* rationalizations for agency action" may not be raised in a brief), the Supreme Court, Federal Circuit and CCPA have long made clear that the PTO may not add new grounds of rejection in procedural postures where an applicant has less than an opportunity to respond "in a meaningful time, in a meaningful manner" to all issues raised.[3] There is no statutory

[3] *Barry v. Barchi*, 443 U.S. 55, 66 (1979) (due process requires an "opportunity to be heard … at a meaningful time and in a meaningful manner."); *Patlex Corp. v. Mossinghoff*, 771 F.2d 480, 483, 226 USPQ 985, 987 (Fed. Cir. 1985) ("administrative convenience or even necessity cannot override the constitutional requirements of due process.")

grant of authority to the Office to depart from established administrative law and Constitutional Due Process here.

Further, the CCPA and Federal Circuit have addressed similar situations on a number of occasions, and have uniformly found that the statute requires that any authority to enter new grounds of rejection exists only where the applicant has a "meaningful" opportunity to respond. For example, *In re McDaniel*, 293 F.2d 1379, 1385, 63 USPQ2d 1462, 1466 (Fed. Cir. 2002) the Federal Circuit reminded the Board of the "statutory mandate that the Board review 'adverse decisions of the examiners upon applications for patents,' 35 U.S.C. § 6(b), and may not affirm or reverse issues that first arise during appeal, at least when the Office closes access to rights to respond. *In re Oetiker*, 977 F.2d 1443, 1445-46, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) (contrasting approval of the examiner's introduction of new grounds during "initial examination" while the applicant had an opportunity to respond, against disapproval of the Office's introduction of new grounds while an applicant's opportunities to respond are closed); *In re De Blauwe*, 736 F.2d 699, 706 n. 9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) ("[W]here the board advances a position or rationale new to the proceedings, as it is empowered to do and quite capable of doing, the appellant must be afforded an opportunity to respond to that position or rationale by the submission of contradicting evidence. … The board's refusal to consider evidence which responds to such a new rationale is error.") This is especially true where an applicant's "ability to refile is non-existent,"[4] for example because of the new Continuations Rule. The Office may not rewrite the statute by rule: when an examiner adds a "new ground" in an Examiner's Answer, that triggers the full cascade of rights to reply.

Further, it must be kept in mind that "new grounds of rejection" in an Examiner's Answer are caused by omissions by the Office, not by any fault of an

[4] *Ex parte Raychem Corp.*, 17 USPQ2d 1417, 1426 (BPAI 1990).

applicant. It is arbitrary and capricious to penalize an applicant for the Office's omissions or late action, or to give examiners further ability and authority to play "hide the ball" during initial examination, and then spring new positions on appeal.

The asymmetry of the proposed Appeal Rules, particularly when combined with the Continuations Rule and the lack of oversight of examiners, is arbitrary and capricious. The trend of the last few years has been to progressively relieve examiners from duties of "compact prosecution," and make the Board a tribunal of first instance. If examiners are to be given more and more procedural laxity, the Office should not impose tighter and tighter limits on applicants' and appellants' procedural opportunities to obtain the patents that the law guarantees. In combination with the Continuations Rule and the Office's repeated statements that it will not enforce examination procedure,[5] this grant of authority to examiners is arbitrary and capricious. If examiners are given the opportunity to raise new grounds of rejection at any time, to introduce new evidence on appeal, to argue with no page limits and no limit on their "legal innovation," it is arbitrary and capricious to force applicants to proceed on a closed record with extremely limited opportunity to reopen through continuation practice and limited space to reply.

B. Procedural Protections Should Not be Conditioned on the Soundness of Examiners' Legal Judgment

Proposed Bd. R. 41.39(a) proposes to condition certain procedural rights for an appellant on an examiner's recognition and designation that he/she has introduced a "new rejection" (or "new ground of rejection").

Very few in the examining operation, including few T.C. Directors, are lawyers,[6] and very few recognize the legal definition of "new ground of rejection," or

---

[5] See § VII.C.4.

[6] John Whealan, Duke University School of Law, 5th Annual Intellectual Property Symposium, http://realserver.law.duke.edu/ramgen/spring06/students/02172006a.rm, at

even the need to consult written precedent to determine the definition accurately. *See*, *e.g.*, Attachment B. Conditioning appellants' rights to appeal on legal judgments by the examining operation is arbitrary and capricious.

The concerns of § VI.A are applicable here as well.

Some of the problem could be partially attenuated by adding a discussion of the definition of "new [ground of] rejection" to the MPEP, as we suggest in Attachment F. However, overwhelmingly, appeals arise out of examiner error, see Attachments C and D, and § VII.C.4, below, and there should be no further conditioning of relief from those burdens on the judgment of that same examiner.

C. New Grounds Raised by Examiner and Board

Proposed Bd. R. 41.50(c)(1) should be clarified as follows

> (b) *New ground of rejection*. Should the Board have a basis not involved in the appeal for rejecting any pending claim, or affirm any new ground of rejection introduced by the examiner after the decision from which the appeal is taken, it may enter such as a new ground of rejection. …

As noted in § V.A, the Office does not have the authority to require appeal from an Examiner's Answer, only from an examiner's action. This has been frequently reiterated by the CCPA and Federal Circuit, that new grounds may only be raised in contexts where an appellant has a reasonably symmetric right to respond with amendments, affidavits, or other rebuttal. *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005) (where the Board provided "simply an additional explanation," that "had not previously been identified by the examiner or the Board," the appellant "was entitled to respond to these calculations, and the Board committed procedural error in refusing to consider the evidence proffered in response."); *In re DeBlauwe*, 736 F.2d 699, 706 n. 9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) ("Where the board makes a decision advancing a position or rationale new

---

59:40: "I don't want to blast the employee work force of the patent office, but we basically hire 22-year-old people without law degrees to examine patent applications. And that's a little scary."

to the proceedings, an applicant must be afforded an opportunity to respond to that position or rationale by submission of contradicting evidence"); *In re Eynde*, 480 F.2d 1364, 1370-71, 178 USPQ 470, 474 (CCPA 1973) ("We do agree with appellants that where the board advances a position or rationale new to the proceedings… the appellant must be afforded an opportunity to respond to that position or rationale by the submission of contradicting evidence… The board's refusal to consider evidence which responds to such a new rationale is error."). The Office may not create loophole through which an examiner may introduce a new ground that should have been fully developed earlier, and place procedural handcuffs on an appellant's ability to respond.

We recognize that the Office must raise rejections whenever they are recognized. However, the only procedurally-adequate way to do so is to give applicants full benefits of continued prosecution when this occurs. If the Board affirms on a ground newly-raised in an Examiner's Answer, the full protections of Bd. R. 41.50(d) should result.

VI. Reply Brief

A. The Scope of Arguments in Reply Brief Should Not be Limited

The restriction of Proposed Bd. R. 41. 41(d) to only "responding to points made in the examiner's answer" would be plausible in a historical and experiential vacuum. However, we have empirical experience that this rule is unworkable. Through the mid-1990's, an appellant's reply brief could only reply to "new grounds of argument" raised in an Examiner's Answer. This led to a great deal of satellite petition practice when examiners tried to exclude Reply Briefs. The authority for examiners who lack legal training to edit appellants' briefs was withdrawn in the late 1990's. As we discussed in § V.B, the vast majority of examiners and T.C. Directors lack the legal training to make the judgment called for in Proposed Bd. R. 41. 41(d),

as the Office itself acknowledged a few years ago. The Office should not repeat failed experiments.

If examiners are free to "include a new rejection," why are applicants denied an opportunity to add a new ground of rebuttal to earlier issues, for example, in light of new case law? There are no limits on supplemental examiners' answers set forth in Proposed Bd. R. 41.43 – the asymmetry throughout this Notice is arbitrary and capricious.

B. Requests for Continued Examination in Response to Untimely New Grounds of Rejection

At page 41480, the preamble to the Notice of Proposed Rulemaking states that in the event that the examiner adds a new ground that could have and should have been raised during regular examination, but was not, and is late added for the first time in an Examiner's Answer, "if an appellant … believes that an amendment is appropriate, the appellant may file a request for continued examination…"

The actual text of Rule 41.41(i) fails to implement the rationale of the preamble, because it omits a statement that the appellant is given an unconditional waiver from the new Continuation rule to reply to untimely action by the examiner. This provision must be added to the express text of 41.41(i).

VII. The Notice of Proposed Rulemaking Exceeds the Office's Rulemaking Authority and Violates Rulemaking Procedure

A. The Office May Not Shift of Burden of Proof

Proposed Bd. R. 41.37(o) should be amended as follows (underlines for additions, strike-through for deletions), with similar amendments to Bd. R. 41.41 and other rules:

> (o) *Argument*. The "argument" shall explain why the examiner is believed to have erred as to each rejection to be reviewed. Any explanation must address all points made by the examiner with which the appellant disagrees and must identify where the argument was made in the first instance to the examiner or

state that the argument has not previously been made to the examiner. ~~Any finding made or conclusion reached by the examiner that is not challenged will be presumed to be correct.~~ Each rejection shall be separately argued under a separate heading. …

(4) *Rejection under 35 U.S.C. 112, first paragraph*. For each rejection under 35 U.S.C. 112, first paragraph, the argument shall also specify the errors in the rejection. If the Office Action states a *prima facie* case under law, the Appeal Brief should specify how the rejected claims comply with the first paragraph of 35 U.S.C. 112 including, as appropriate, how the specification and drawings, if any, describe the subject matter defined by the rejected claims, enable any person skilled in the art to which the invention pertains to make and use the subject matter of the rejected claims, or set forth the best mode contemplated by the inventor of carrying out the claimed invention.

(5) *Rejection under 35 U.S.C. 112, second paragraph*. For each rejection under 35 U.S.C. 112, second paragraph, the argument shall specify the errors in the rejection. If the Office Action states a *prima facie* case under the law, the Appeal Brief should specify how the rejected claims particularly point out and distinctly claim the subject matter which appellant regards as the invention.

(6) *Rejection under 35 U.S.C. 102*. For each rejection under 35 U.S.C. 102 (anticipation), if the reference relied on by the examiner is prior art and the Office Action states a *prima facie* case under the law, the argument shall also specify why the rejected claims are patentable by identifying any specific limitation in the rejected claims which is not described in the prior art relied upon in support of the rejection.

(7) *Rejection under 35 U.S.C. 103*. For each rejection under 35 U.S.C. 103, ~~if appropriate,~~ the argument shall specify the errors in the rejection and, if appropriate, specify the specific limitations in the rejected claims that are not described in the prior art relied upon in support of the rejection, or explain how the references fail to provide reason to modify or combine, or fail to provide reasonable expectation of success, or otherwise ~~and~~ explain how those limitations render the claimed subject matter unobvious over the prior art. A general argument that all limitations are not described in a single prior art reference does not satisfy the requirements of this paragraph.

(8) *Other rejections*. For each rejection other than those referred to in paragraphs (o)(4) through (o)(7), the argument shall specify the errors in the rejection, including where appropriate, the specific limitations in the rejected claims upon which the appellant relies to establish error.

At several points, the Proposed Bd. R. 41.37 and 41.41 shift the burden of proof to the appellant to demonstrate patentability, rather than merely to demonstrate error in the examiner's position. This is problematic in at least two respects.

First, any rule that would shift either the burden of proof or the burden of production to patent applicants is in direct violation of Supreme Court jurisprudence. *See*, *e.g.*, *Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers*, 512 U.S. 267, 275-81 (1994). The APA prohibits an agency from shifting by rulemaking the burden of proof or persuasion of issues for adjudications. In such cases, the rule is invalid under 5 U.S.C. § 556(d) ("Except where otherwise provided by statute, the proponent of a rule or order has the burden of proof."); *Director, Office of Workers Compensation Programs*, 512 U.S. at 275-81 (unless superseded by statute, § 556(d) prohibits an agency from shifting the burden of persuasion regarding issues the agency is required to prove in order to grant or deny an order). The burden-shifting provisions of proposed Bd. R. 41.37(o)(4) – (8) may not be promulgated.

Second, any attempt to shift of a burden of proof is "substantive," and therefore outside the PTO's authority. *Director, Office of Workers' Compensation Programs, Dept of Labor v. Greenwich Collieries*, 512 U.S. 267, 271 (1994) ("[T]he assignment of the burden of proof is a rule of substantive law."). The PTO does "NOT … have authority to issue substantive rules," 35 U.S.C. § 2(b)(2)(A); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550, 38 USPQ2d 1347, 1351 (Fed. Cir. 1996) (emphasis in *Merck*). The burden-shifting provisions of proposed Bd. R. 41.37(o)(4) – (8) may not be promulgated.

Third, the burden of establishing a *prima facie* rejection is always on the PTO. *In re Oetiker*, 977 F.2d 1443, 1445-46, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) ("the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. … If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." emphasis added). The PTO has no authority to demand that appellants demonstrate patentability. The Office may not require an appellant to do anything more than point out the examiner's error. In

many cases, an appeal is soundly addressed solely to the examiner's failure to identify any correct legal principle, or any "substantial evidence" in support. Appeal Rules should not force an appellant to burden the Board with more argument than required to remove the rejection.

Fourth, the Office may not impose "presumptions" The burden is on the Office to establish all facts on which it relies, and to support them with substantial evidence. This sentence of the proposed rule is contrary to law. The APA prohibits an agency from shifting by rulemaking the burden of proof or persuasion of issues for adjudications. In such cases, the rule is invalid under 5 USC. § 556(d) ("Except where otherwise provided by statute, the proponent of a rule or order has the burden of proof."). See, e.g., *Director, Office of Workers Compensation Programs, Dept. of Labor v. Greenwich Colliers*, 512 U.S. 267, 275-81 (1994) (unless superseded by statute, Section 556(d) prohibits an agency from shifting the burden of persuasion regarding issues the agency is required to prove in order to grant or deny an order). *St. Mary's Honor Center v. Hicks*, 509 U.S. 502, 510-11 (1993) (a rebuttable presumption, "having fulfilled its role of forcing the [other party] to come forward with some response, simply drops out of the picture").

B. The Office Admits it Exercised "Substantive Judgment," Rendering the Extension Rule "Substantive" and Therefore Outside the Office's Authority

Under the law of some of the Courts of Appeals, a rule is "substantive" when it "encodes a substantive judgment" of an agency. In other circuits, a rule is "substantive" when it has "substantive effects." This Rulemaking meets either test, and is thus "substantive" and beyond the Office's authority. The preamble to the Notice of Proposed Rulemaking expressly confesses that the agency has a substantive preference, and is embedding it in Proposed Bd. R. 41.41(c):

> The Office does not believe that an applicant should be able to add any patent term adjustment by the automatic extensions of time that are available through Rule 136(a).

This expression of "belief" on a substantive issue renders Rule 41.41(c) "substantive" and therefore outside the Office's authority.

Further, 35 U.S.C. § 154(b)(2)(C)(i) provides that the Office must provide three months to reply to any Office paper before it may attenuate patent term protections. The preamble states that the Office "believes" it should cut off term protections at two. The Office is entitled to any "belief" it wants, but it is not permitted to give effect to its difference of opinion with Congress in a rulemaking notice.

C. Executive Order 12,866

The Office designation of the proposed Appeals Rule as "not significant" under Executive Order 12,866 is incompatible in every respect with the plain language of the Order. The proposed rule is substantive action (PTO's assertions notwithstanding); it is "significant" (it materially affects the most innovative sectors of the economy); and it imposes annual costs of approximately $100 million.

1. The Designation "Not Significant" Reflects Badly on PTO Understanding of Rulemaking Process

The designation "not significant" is reserved for mundane actions that engender no controversy, and thus are not worthy of oversight by the federal government's in-house regulatory watchdog. Executive Order 12,866 delegates to the agencies the responsibility for behaving responsibly – to police their own regulatory development operations and ensure that significant proposed regulations are managed in accordance with this long-established process.[7]

[7] This process has been in place for 14 years, plenty of time for USPTO to have garnered a sophisticated understanding of the procedures and the ability to discern a significant draft rule when it sees one. From 1981 until 1993, ***all*** draft rulemakings were required to be submitted OMB for review. The PTO's decision to brazenly flout these established procedures signals that it no longer deserves any deference in these determinations.

2. The Costs Are "Significant" and Likely "Economically Significant"

The costs of the proposed Appeals Rule are certainly "significant," and likely "economically significant." For example, just one rule element – the appendix and pagination of Proposed Bd. R. 41.37(v)(1) – is estimated to impose costs exceeding $ 28 million per year. See § III.B. The new elements required in the "argument" and the appendices are at least as large. The totals approximate $100 million per year.

These costs are just paperwork burdens. The most significant cost of the proposed Appeal Rules is the value of patent protection foregone due to added costs, procedural complexity, and legitimate claims that must foregone to satisfy the Board's new and arbitrary requirments. In short, the proposed Appeals Rule is almost certainly economically significant, requiring the Office to perform a Regulatory Impact Analysis in accordance with OMB Circular A-4. See Attachment H.

3. This Rulemaking Breaches Executive Order 12,866 by Failing to Consider How "Existing Regulations (or other law) have Created, or Contributed to" the Problem the PTO Seeks to Solve, or are in "Conflict" with Other Regulations

Executive Order 12,866 (as amended)[8] § 1(B)(10) says:

> Each agency shall avoid regulations and guidance documents that are inconsistent, incompatible, or duplicative with its other regulations and guidance documents." E.O. § 1(b)(2) requires every agency, for every rulemaking, to "examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct.

The PTO has admitted that the proposed Appeal rule is intended to cure a problem that the PTO itself created with the recently-finalized Continuations Rule, and implicitly admits that the Appeal Rule is intended to deter applicants from availing themselves of appellate rights that are even more crucial because of the Continuations Rule.

---

[8] http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf

In the preamble to the proposed rule, the PTO states that its purpose is "to permit the board to handle an increasing number of ex parte appeals in a timely manner." See 72 Fed. Reg. 41472, col. 1. But this declaration is disingenuous. It does not acknowledge that the Board expects a 25% increase in appeals in FY 2008 (5,000) over FY 2007 (4,000) because of the recently promulgated Continuations Rule. The PTO said so in its FY 2007 budget request, in which it sought over $8 million in FY 2008 to fund additional Administrative Patent Judges and supporting staff, rising to more than $14 million in FY 2011:

> [D]uring fiscal year 2007, the Board of Patent Appeals and Interferences (BPAI) anticipates it will begin to receive an increased level of appeals following continuation rulemaking to bring greater finality to patent application prosecution. Based on existing assumptions, the office anticipates BPAI's appeal workload to increase by approximately one-third.

See PTO, *Fiscal Year 2007 Budget* at 32 (http://www.uspto.gov/web/offices/ac/comp/budg/fy07pbr.pdf). The PTO sought million s of dollars in new funding to deal with a problem that it knew it was causing by abbreviating continuations practice. Now it proposes to take away the very circuit breaker that applicants need to make the Continuations Rule even minimally workable. The proposed regulation has no conceivable relationship to the underlying cause for the particular problem the regulation is supposed to solve, and therefore violates E.O. 12,866.

The PTO admits that any additional burden on the Board is caused by the PTO itself, and specifically by the Continuations Rule. The PTO must find a way to internalize the costs of the burdens it creates for itself. It is counterproductive and disingenuous for the PTO to pass the costs of its own management errors and unwise rulemaking on to inventors.

4. This Rulemaking Violates Executive Order 12,866 by Failing to Consider How the PTO's "Existing *Interpretations of* Regulations (or other law) have created, or Contributed to" the Problem The PTO Seeks to Solve, and Failing to Observe the President's "Good Guidance Practices"

Executive Order 12,866 (as amended)[9] § 1(b)(2) requires every agency, for every rulemaking, to "examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively." The problem the agency seeks to solve lies squarely with the examination management's incorrect interpretation of the following regulations and laws: (a) management's duty to "manage and direct" "all aspects" of examination," 35 U.S.C. § 3(b)(2)(A), (management believes that the statute's "all" means something less than "all"), (b) the duty to "cause an examination to be made" and "state reasons" under 35 U.S.C. §§ 131 and 132, and (c) the scope of appealable subject matter, and therefore an incorrectly-narrow view of the scope of subject matter petitionable under 37 C.F.R. § 1.181(a)(1).

The proposed Appeal Rules could be obviated if the Office simply followed the President's instructions, and implemented longstanding Federal Circuit law on the duty of the Director and Commissioner to use the petitions process to oversee discretionary and procedural acts of examiners, even when they relate to claims, and implemented recent Executive Orders and the Final Bulletin for Agency Good Guidance Practices, and related Presidential instructions.[10] Instead of enforcing

---

[9] http://www.whitehouse.gov/omb/inforeg/eo12866/eo12866_amended_01-2007.pdf

[10] Executive Order 12,866, 58 Fed. Reg. 51735-51744 (October 4, 1993, http://www.whitehouse.gov/omb/inforeg/eo12866.pdf); Executive Order 13,422, 72 Fed. Reg. 3432 (Jan. 25, 2007, http://www.whitehouse.gov/omb/inforeg/eo12866/fr_notice_eo12866_012307.pdf); "Final Bulletin for Agency Good Guidance Practices" (OMB Memorandum M-07-07, January 18, 2007, http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf); and "Implementation of Executive Order 13422 (amending Executive

procedural requirements relating to examination of claims, on August 21, 2007, Director Dudas expressly and categorically announced his refusal to provide "supervisory review" of violations of agency guidance requirements, even where that intra-agency guidance is set forth in "procedural terms."[11] The Petitions Office, in (what the Office asserts, but with no citation to any written document to support the assertion) as a longstanding (but unpublished) policy of refusing to honor the Federal Circuit's instructions that applicants are "entitled to rely" on the MPEP,[12] insists that the Office refuses to enforce the PTO's own guidance document.[13] The Office's disagreement with Presidential directive, refusal to honor its own procedural promises, and refusal to follow its reviewing court's precedent, is alarming.

The PTO's own statistics[14] and our experience suggest that the Office's current backlog crisis is overwhelmingly caused by administrative unpredictability resulting from the examining operation's lack of regard for procedural law and agency guidance. Attorneys read the MPEP and know that it states rules that they are "entitled to rely" on to predict the Office's future course, and their ethical obligations to clients limits their ability to surrender property rights that the Office is legally

---

Order 12866) and the OMB Bulletin on Good Guidance Practices" (OMB Memorandum M-07-13, April 25, 2007, http://www.whitehouse.gov/omb/ memoranda/fy2007/m07-13.pdf).

[11] Notice of Final Rulemaking, Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46715, 46752 col. 2-3 (Aug. 21, 2007).

[12] *In re Kaghan*, 387 F.2d 398, 847-48, 156 USPQ2d 130, 132 (CCPA 1967) ("we feel that an applicant should be entitled to rely not only on the statutes and Rules of Practice but also on the provisions of the MPEP in the prosecution of his patent application").

[13] *E.g.*, Decisions on Petition in App. Serial No. 09/385,394 of summer-fall 2003 and fall 2005, taking no issue with the showings that the examiner breached multiple "must" directives set forth in the MPEP, yet refusing to enforce those requirements, and refusing to protect the applicant from the adverse consequences flowing from the examiner's breach of those requirements.

[14] See Attachments C and D.

obligated to provide. When an examiner refuses to comply with the MPEP, extended prosecution and appeal are the result.

We find that many of our appeals arise out of an examiner's *silence* on required issues. As one example, in U.S. App. Ser. No. 09/611,548, four successive Office Actions were dead silent on the same claim language, violating both the MPEP § 2143.03 requirement to discuss every claim limitation, and MPEP § 707.07(f) requirement to "Answer All Material Traversed." For seven years, it was not clear whether applicant and examiner were reading the claims differently, whether they were reading the references differently, whether they had different views of the law, or different views of the application of the law to the facts. Similarly, very few (if any) "subject matter" rejections flowing from Art Units 3690 in recent months have made showings of "abstract idea, law of nature or natural phenomenon" and lack of "useful, concrete and tangible" as required by MPEP § 2106; instead, almost all rely on *ad hoc* legal tests made up by the examiner. Appeal can be no more "focused" than the examiner's papers and development of the issues. Applicants have no unilateral ability to get applications into condition for efficient and "focused" appeal when examiners are under no obligation to "focus" or use predictable procedures for examining claims.

SPE's often refuse to enforce procedural rules, in the mistaken belief that they have no obligation to do so because they think that the obligation to enforce procedure lies with the Board. Attachment A is an interview summary with an SPE, in which she explained her view that procedure was unimportant and would not be enforced in her art unit. This is merely one representative of a number of other conversations with other SPE's – procedure is viewed as something entirely optional by far too many examiners, SPE's, and T.C. Directors.

Similarly, T.C. Directors (who are not required to be "persons of competent legal knowledge") have less than full respect for the rule of procedural law. Attachment B is a summary of an interview with a T.C. Director after he had

dismissed a petition for premature final rejection because he insisted that final rejection was an appealable issue. In the interview, he (a) refused to accept either the Board's or the MPEP's statement that premature finality is a petitionable issue, (b) expressed the view that procedure does not "matter," (c) refused to inform himself of the Office's and courts' statements of law, and (d) in subsequent papers, refused to enforce any procedural requirements and acknowledged that his policies affirmatively incentivized examiners to "short cut" the rules.

The Board is equally clear that it has neither supervisory responsibility nor power, *see* Attachment E, footnotes 30 and 34, leaving examiners with no supervisory oversight in the procedural elements of examination of claims.

This lack of observance of procedure during initial examination has a large effect on efficiency of examination. Because examiners fail to observe procedural requirements to ask the right questions, they often reach wrong answers. The overwhelming majority of appeals arise out of examiner error, not applicant error. Attachment D is a spreadsheet calculating affirmance rates, based on statistics available on the Board's web page and obtained by FOIA request, showing that examiners are affirmed less than 20% of the time – an **error rate of 80%**.[15] Other studies have shown examiner error rates of **90%**.[16] No other organization would tolerate this kind of error rate, let alone blame its customers for its own errors as the PTO has done in the last two years' rulemakings.

The proposed Appeal Rules have no rational connection to the underlying cause for the problem identified. They do nothing to address the source of the problem, but instead force more costs on the innocent party, the party in least

---

[15] The rise in affirmance rate for FY 2006 may be due to the "Pre-Appeal Review" program. The number of rejections vacated and reversed in this program are not reflected in the statistics obtained. Thus, the FY 2006 statistics overstate the number of affirmance.

[16] AIPLA's letter on the Continuations Rule, http://www.uspto.gov/web/offices/pac/dapp/opla/comments/fpp_continuation/aipla.pdf at page 11.

position to add "focus" to the examination process. If the Office enforced and followed its *procedural* guidance during *examination*, as the President's Good Guidance Practices require, many of the Office's and the Board's backlog problems would disappear quickly.

We suggest that a far more effective approach to reduce the number and increase the efficiency of appeals would be to implement procedures by which applicants could ensure procedurally complete examination in the first instance, thereby removing much of the need for either continuations or appeals. As we note in § VIII.B, above, and Attachment E, that could be achieved by a clear statement of the limits of the Board's jurisdiction (thereby clarifying the obligation of petitions officials to decide non-appealable petitions under 37 C.F.R. § 1.181(a)(1)), and the obligation of line management to "cause an examination to be made" under 35 U.S.C. § 131.

D. Regulatory Flexibility Act

The proposed Appeal Rules include several substantive aspects, as discussed in §§ II.A and § VII.A. That brings the Appeal Rule within the purview of the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq* ("RegFlex").

Further, the exceptions to the notice-and comment requirement of 5 U.S.C. § 553 are "narrow" and should be "construe[d] as an attempt to preserve agency flexibility in dealing with limited situations where substantive rights are not at stake." *American Hospital Assoc. v. Bowen*, 834 F.2d 1037, 1044-45 (D.C. Cir. 1987). The exceptions apply only where the interests "promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition and reduction in expense." *Guardian Federal Savings & Loan Ass'n v. FSLIC*, 589 F.2d 658, 662 (D.C. Cir. 1978). Consistent with these principles, the procedural rule exception applies only to "internal house-keeping measures

organizing agency activities." *Bowen*, 834 F.2d at 1045. Measured against that test, the Appeal Rules require notice and comment, and therefore a full RegFlex analysis.

The PTO's RegFlex certification consists in its entirety of the following "analysis:"

> The USPTO received approximately 443,000 patent applications in Fiscal Year 2006. The proposed rules apply only to those applications where an appeal brief is filed with the Board. In Fiscal Year 2006, approximately 18,500 appeal briefs were filed. Of those 18,500 appeal briefs, approximately 4,000 were filed by small entities. Thus, the number of small entities affected by these proposed rule changes is not substantial (approximately 0.9%). Also, the proposed rules do not disproportionately impact small entities.

See 72 Fed. Reg. 41484, col. 1. Dividing 4,000 appeals by small entities by the 443,000 applications filed by all entities to arrive at "the number of small entities affected" is simply amateurish. By the PTO's own statistics, 22% of appeals (4,000 ÷ 18,500) are filed by small entities. It is inconceivable that 22% does not exceed the threshold for disproportionate impact.

Also, the RegFlex certification of the effect on direct appeals fails to reflect an understanding of basic procedural and economic facts: if the deck is substantially restacked for appellate review, there will be a substantial back-pressure effect on proceedings in the proceedings before the examiner.

Restricting the availability of appeal (especially in combination with restrictions on continuations and claims) sharply changes the ability of applicants to obtain the patent protection provided by law. The PTO simply ignores these economic effects by pretending that the Notice of Proposed Rulemaking is "not significant" under Executive Order 12,866.

E. Information Quality Act

A number of statements in the Notice of Proposed Rulemaking violate the PTO's Information Quality Guidelines[17] requirements for objectivity and utility, and

[17] http://www.uspto.gov/web/offices/ac/ido/infoqualityguide.html

requirements under the Administrative Procedure Act for a rational connection between a regulation and the problem sought to be regulated. The following statements in the Notice at 72 Fed. reg. 41479, col. 3, are illustrative examples:

- "The Board is currently experiencing a large increase in the number of ex parte appeals" from 3,349 in FY 2006 to 5,000 expected in FY 2008.

What is the basis for this projection? What is the underlying cause for over 50% growth in two years? How do these rules have anything whatsoever to do with that underlying cause?

- "The provisions of Rule 136(a) are not consistent with efficient handling of appeals after the time an appeal brief is filed."

Efficient for whom? Based on what theory and evidence?

F. Paperwork Reduction Act: The Proposed Rule Includes an Illegal Information Collection

Proposed Bd. R. 41.37(t) and (u) would require appellants to repackage and re-submit, among other things, each of the following documents:

- "The Office action setting out the rejection on appeal…" Bd. R. 41.37(t)(2).
- "the Office action incorporated by reference" Bd. R. 41.37(t)(2).
- "All evidence relied upon by the examiner…" Bd. R. 41.37(t)(3).
- "The relevant portion of a paper filed by the appellant before the examiner…" Bd. R. 41.37(t)(4).
- "Affidavits and declarations…" Bd. R. 41.37(t)(5).
- "Other evidence…" Bd. R. 41.37(t)(6)
- "Copies of orders and opinions" for related cases, even those decided by the PTO itself. Bd. R. 41.37(u)

Under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. (PRA), the Office of Management and Budget cannot approve Information Collection Requests that are duplicative:

> To obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:
>
> > (i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;
> >
> > (ii) Is not duplicative of information otherwise accessible to the agency; …

See 5 C.F.R. § 1320.5(d)(1). Each and every item on this list will already exist in the file. Proposed Bd. R. 41.37(t) ("The 'evidence section' shall contain only papers which have been entered by the examiner.") Therefore, these information collection demands are unambiguously duplicative. Not only is the requested information *accessible* to the Board, it is maintained electronically by the PTO in a form and format that the PTO itself prescribed.[18] This requirement is illegal.

New paperwork burdens which are not illegal are unduly burdensome because they are transparently punitive and provide no demonstrated practical utility even to the Board. The proposed rule specifies detailed and picayune requirements for format, margins, type font, font size, location of attachments and tables, and other matters. If an appellant fails any of these requirements, the Office threatens to reject the appeal for nonsubstantive reasons. OMB by law must balance burden and practical utility, and must state that balancing in the Notice of Proposed Rulemaking to solicit meaningful comment. Having failed to do so, the PTO may not promulgate these rules without, at a minimum, a new round of Notice and Comment.

VIII. Alternative Recommendations

A. Compliance with Recent Executive Orders

The Board and applicants share a common problem – indiscipline among examiners. This, in turn, flows from management's failure to implement both

[18] Under OMB's section 1320.5(d)(ii), it would not matter if the Board were a separate federal agency from the PTO. The Board could not impose the duplicative requirement as long as the same information is accessible from the PTO.

longstanding law and recent Executive Orders requiring management to compel examiners to follow the Office's guidance documents. The Board should work with the management of the examining operation to enforce procedural regularity, and the quality of Office Actions, so that applications can be efficiently resolved during § 131/132 examination. This would both reduce the number of appeals and improve the quality of the record presented to the Board for review. Either the examination process must be reformed to ensure that examiners examine according to predictable procedures, or the appeal process must retain flexibility for applicants to deal with all examiner errors.

The President's Final Bulletin for Agency Good Guidance Practices, and related Presidential instructions are discussed in § VII.C.4.

B. Alternative Recommendation: a "Restatement" of the Scope of "Appealable Subject Matter" Would Reduce Many Problems

Proposed Bd. R. 41.31(e) states, circularly, that "A non-appealable issue is an issue not subject to appeal under 35 U.S.C. 134." A "Restatement of the Law" of the Board's § 134 jurisdiction would be immensely helpful to appeals, and more importantly, to efficient examination.

Unfortunately, the examining operation has a very different opinion of the jurisdictional divide than the Board, and the lack of agreement leaves a large "no man's land" of *procedural* issues underlying rejections of claims where examiners operate with no supervision or oversight from either the Board or the Director. For example, a number of Tech Center SPRE's and Tech Center Directors believe that "premature final rejection" is an appealable issue because it relates to claims, and thus examiners have little constraint or guidance. See Attachments A and B.

Most statements of the Board's jurisdiction are very difficult to locate. For example, a private email received from Chief APJ Stoner a few years ago, unpublished decisions, and intermediate appeals decisions that are not searchable on the Board's web page or decisions that have never been made public. We have

attempted to collect the public and non-public statements of the Board's jurisdiction of which we are aware in a way that could be added to MPEP § 1201. That proposed "Restatement" is presented as Attachment E, which we recommend for incorporation into the MPEP.

The high rate of successful appeal, and the extraordinarily low rate of affirmance for examiners (in the range of 10-20%, see Attachments C and D and § VII.C.4, below), suggest that the cause for the Board's "unwanted popularity" lies in defects within the examining operation. The Board should not, and cannot, be the primary entity enforcing proper application of the law during examination. Rather, PTO management, having exerted great and careful effort to produce Chapter 2100 of the MPEP, should enforce it by requiring examiners to set forth findings on all *prima facie* issues required by the MPEP. Once an examiner states a position, it's almost always easy to diagnose the error (whether it lies with applicant or examiner) and resolve the issue. The problem is the pervasive *silence* of the examining operation, and frequent application of "rules" that have no basis in any written document. Clarifying the scope of the Board's jurisdiction will appropriately define the breadth of management's duty to "manage and direct" the examining operation. 35 U.S.C. § 3(b)(2)(A). That will be more efficient for all concerned, and save the Board from its backlog problem.

IX. The Proposed Rules Exacerbate the Underlying Problems and Remove Applicants' Ability to Have PTO Errors Corrected

We fully appreciate that the Board has been placed in an unenviable position, and that the proposed Appeal Rules are entirely a reaction to non-Board forces. However, the proposal does not address the underlying source of the problem in a way that is fair and leads to quality adjudication.

The PTO has revealed that it is engaged in a now-obvious bait-and-switch strategy. The Office's key rationale for the recently-finalized Continuations Rule was

the availability, ease and efficiency of appeal for appellants, and the Office strongly encouraged appeal rather than continuations. *E.g.*, 72 Fed. Reg. 46716, 46720, col. 2, par. 3 to col. 3 par.1 ("The Office also appreciates that applicants sometimes use continued examination practice to obtain further examination rather than file an appeal… the appeal process offers a more effective resolution than seeking continued examination before the examiner.")

The proposed Appeal Rules, if promulgated, would destroy the limited rights to full and fair examination the PTO promised would be preserved after it shut down continuations practice. It would substantially increase the cost of appeal and severely restrict appellants' ability to present their cases or obtain a full and fair adjudication of patentability. Having relied on a fairly adjudicated appeals process to justify curtailment of continuations practice, the PTO now proposes to prevent as many applicants as possible from exercising these appeal rights.

Finally, it is significant that the PTO withheld public disclosure of the proposed Appeals Rule until July 30. That's 21 days after OMB concluded its review of the draft final Continuations and Claims Rules. Unlike OMB, the PTO surely knew that the proposed Appeals Rules were highly relevant to the Continuations and Claims Rules and that its provisions would be fundamentally inconsistent. It also explains why the PTO sought to evade OMB oversight by falsely designating the proposed Appeal Rules as "not significant" under Executive Order 12,866.

X. The "Record on Appeal"

Proposed Bd. R. 41.30 proposes that the record would begin with the appellant's appeal brief. This is not correct. An appeal is from the "decision of the examiner," 35 U.S.C. § 134, not from the Examiner's Answer. The examiner's last Office action, and the "at most one" action incorporated by reference, must be part of the record as well.

XI. This Letter is Timely

Leave to file this paper after October 1, 2007 was granted via an email to the undersigned:

From: McKelvey, Fred [mailto:Fred.McKelvey@USPTO.GOV] **On Behalf Of** BPAI Rules
Sent: Monday, October 01, 2007 3:41 PM
To: Boundy, David - Cantor Fitzgerald
Subject: RE: Request for extension of Notice and Comment

2 weeks

From: Boundy, David - Cantor Fitzgerald [mailto:DBoundy@cantor.com]
Sent: Monday, October 01, 2007 3:02 PM
To: BPAI Rules
Subject: RE: Request for extension of Notice and Comment

Thank you. Do you have an estimate - say one week vs 2 vs 3?

From: McKelvey, Fred [mailto:Fred.McKelvey@USPTO.GOV] **On Behalf Of** BPAI Rules
Sent: Monday, October 01, 2007 2:52 PM
To: Boundy, David - Cantor Fitzgerald
Subject: RE: Request for extension of Notice and Comment

Your request for a formal extension of time to comment on the Notice of Proposed Rulemaking, 71 Fed. Reg. 41472 (July 30, 2007) (Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals) has been received. The process of reviewing comments and determining a final rule has begun today, October 1, 2007. While a formal extension of time will not be granted, any comments received before comment review is complete will be considered. Please feel free to submit any comments as soon as possible.

Fred E. McKelvey
Senior Administrative Patent Judge
Board of Patent Appeals and Interferences

A formal extension, properly published in the Federal Register, was requested, as noted in the letter attached at Attachment I.

XII. Conclusion

Desperation should not lead to panicked decision making that violates the observable data, common sense, and the law governing rulemaking. The increase in workload is not the "fault" of the Board. Nor is it (by and large) the fault of applicants. The data we have been able to obtain, our impression as practitioners, and the confession of various supervisory personnel (see Attachments A and B) is that the vast bulk of the Board's workload arises from lax procedural enforcement on the examining side of the Office. The correct resolution of the Board's predicament is for the Board to remonstrate with management to enforce examination procedure, not punish applicants who dare to appeal when the Office commits error. If the Office will not observe the President's Good Guidance Practices directive to impose procedural regularity on examination, then the Appeal Rules must remain reasonably symmetric, to provide fair opportunities for appellants.

Because, as the PTO itself admits, the need for most aspects of this Appeal Rule arise out of the PTO's "existing regulations," and "cumulative regulations," primarily the new Continuations Rule and management's refusal to provide any formal enforcement mechanism for the agency's procedural guidance on examination of claims. Executive Order 12,866 § 1(b) requires the PTO to consider "whether those regulations (or other law) should be modified to achieve the intended goal." The Notice of Proposed Rulemaking reflects no such consideration. Further action

by the PTO is illegal until it has set forth such consideration for public Notice and Comment. The Rule must be reproposed for a new round of Notice and Comment.

Sincerely,

/s/ David E. Boundy

Vice President, Assistant General Counsel Intellectual Property
Cantor Fitzgerald L.P.
499 Park Ave.
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)

/s/ Dean P. Alderucci

COO & Assistant General Counsel
Cantor Fitzgerald, Innovation Division
499 Park Ave.
New York, NY 10022
(212) 829-7009
(212) 294-7789 (FAX)

Attachment A

Interview Summary with SPE Meng Ai An

PATENT

ATTORNEY DOCKET NO. 114596-05-4013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	09/239,194	Confirmation No.:	9716
Applicant:	John S. Yates, Jr., et al.		
Title:	EXECUTING PROGRAMS OF A FIRST COMPUTER ARCHITECTURE ON A COMPUTER OF A SECOND ARCHITECTURE		
Filed:	January 28, 1999		
Art Unit:	2127		
Examiner:	Kenneth Tang		
Atty. Docket:	114596-05-4013		
Customer No.	38492		

I certify that this correspondence, along with any documents referred to therein, is being deposited with the United States Postal Service on July 25, 2005 as First Class Mail in an envelope with sufficient postage addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

David E. Boyle

SUMMARY OF INTERVIEW WITH SUPERVISORY EXAMINER MENG AN

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The undersigned attorney had a telephonic interview with Supervisory Examiner Meng An on Thursday, July 7.

This attorney asked for supervisory intervention regarding the procedural issue of premature final rejection. Supervisory Examiner An stated that she did not consider such issues, that she only considered the merits. Supervisory Examiner An stated that she would not consider granting procedural relief, even if the violation of Patent Office rules complained of was purely procedural.

Supervisory Examiner An stated that she had reviewed the papers and she did not believe that a "new ground of rejection" had been raised. This attorney asked if she had any written rule or publication that supported any definition of "new ground of rejection" that she might be applying. Supervisory Examiner An stated that she did not. This attorney directed Supervisory Examiner An to the definition of "new ground of rejection" stated in *In re Kronig* and *In re Wiechert* and requested that she review the quotes from these cases at pages 1-2 of the Request to Withdraw Finality of Office Action of March 21, 2005. She declined to read that paper. This attorney asked Supervisory Examiner An if she had any basis to disagree with the court's holding in *Wiechert*. She declined to answer the question. This attorney asked Supervisory Examiner An if she had authority to disregard the CCPA. She declined to answer this question.

This attorney twice asked Supervisory Examiner An if she would like to take a couple days to find some written rule that would overrule *Wiechert* or create an exception, or support her view. She stated twice that she would not do so.

Supervisory Examiner An suggested that Applicant should respond in papers. This attorney noted that the position had already been set out in papers, and those papers had been before the examiner twice, once when originally filed in March, once when reconsideration was requested by phone in May. This attorney noted that the examiner's responsive papers had failed to address the procedural issues raised in Applicant's papers, and had failed to provide any requested clarification on the merits. Supervisory Examiner An reiterated that Applicant should respond in papers. This attorney asked Supervisory An why filing the same arguments and requests for clarification a third time would ensure that they received a proper response, when no response had been given them in the past. Supervisory Examiner An declined to answer the question; she simply reiterated her position that a further set of papers should be filed.

Supervisory Examiner An stated that an applicant is responsible for reading the entirety of any reference cited by an examiner (including, apparently, all 144 columns of the Chernoff '028 reference), and that an examiner may freely rely on new portions of an existing reference without introducing a "new ground of rejection." This attorney asked if Supervisory Examiner An knew of any written statement to that effect; Supervisory Examiner An stated that she did not. This attorney invited Supervisory Examiner An to review the quote from *Wiechert* in the Request, which states exactly the opposite of her view. Supervisory Examiner An declined the invitation.

Supervisory Examiner An stated that the issues on the merits should have been addressed by telephone interview with the examiner. This attorney agreed, and noted that an interview with the examiner had been requested on a number of occasions. This attorney noted that the examiner had declined all requests for an interview. We did not reach an agreement for how to proceed on this issue.

Supervisory Examiner An conceded that Examiner Tang's papers were not clear, and yet asserted that clarification of those positions was not a "new ground of rejection." She provided no authority for this definition of "new ground of rejection."

This attorney asked how Supervisory Examiner An made sure that her examiners made correct and fair determinations on the merits, if she enforced no requirements of procedure.

Supervisory Examiner An declined to answer the question; she reiterated that Applicant should file whatever papers were deemed appropriate.

It is believed that this paper occasions no fee. Kindly charge any additional fee, or credit any surplus, to Deposit Account No. 23-2405, Order No. 114596-05-4013.

Respectfully submitted,

WILLKIE FARR & GALLAGHER LLP

Dated: July 25, 2005

By: _____

David E. Boundy
Registration No. 36,461

WILLKIE FARR & GALLAGHER LLP
787 Seventh Ave.
New York, New York 10019
(212) 728-8757
(212) 728-9757 Fax

Attachment B

Interview Summary with T.C. Director Jack Harvey

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	09/385,394	Confirmation No.:	unassigned
Applicant:	John S. Yates, Jr., et al.		
Title:	COMPUTER WITH TWO EXECUTION MODES		
Filed:	August 30, 1999	Art Unit:	2183
Atty. Docket:	114596-03-4000	Examiner:	Richard Ellis

SUMMARY OF INTERVIEW (10/30/2005) WITH T.C. DIRECTOR HARVEY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

An interview was conducted between T.C. Director Jack Harvey and the undersigned attorney by telephone on October 30.

1. This attorney requested clarification of the following sentence from SPrE Johnson's paper of 9/9/2005, page 5, lines 1-3: "[T]here is no requirement for element for element or limitation for limitation identification between the claims and reference(s) be provided to applicant in the grounds of rejection set forth in the examination process." In the interview, this attorney specifically drew T.C. Director Harvey's attention to 37 C.F.R. § 1.104(c)(2), § 1.113(b) and MPEP § 2142-2143.03. T.C. Director Harvey offered no elaboration of his view.

2. Applicant offers the following observations. 37 C.F.R. § 1.104(a) requires that examination "shall be complete." 37 C.F.R. § 1.104(c)(2) requires that "the particular part [of each reference] relied on must be designated as nearly as practicable" and, at least for all obviousness rejections, that "the pertinence of each reference, if not apparent, must be clearly explained." 37 C.F.R. § 1.113(b) requires that all grounds be stated "clearly" before rejection is made final. MPEP § 2142-2143.03 state, for example, that "...it is the duty of the examiner to explain why the combination of the teachings is proper." *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003) requires "examiners ... are responsible for making findings, informed by their scientific knowledge, as to the meaning of prior art references...". *In re Epstein*, 32 F.3d 1559, 1570-71, 31 USPQ2d 1817, 1825 (Fed. Cir. 1995) (Plager, J., concurring) notes that "One

I certify that this correspondence, along with any documents referred to therein, is being deposited with the United States Postal Service on November 28, 2005 as First Class Mail in an envelope with sufficient postage addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dan E. Boal

> function of the PTO's *prima facie* case practice is to force the PTO examiners to set forth specific [rejections], which can be met by the applicant, and not just to make a general rejection."
>
> These rules merely state concrete examples of general principles arising under the Administrative Procedure Act, expressed in Supreme Court and Federal Circuit precedent. *Motor Vehicle Manufacturers' Assn. of the United States Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43, 48 (1983) (every written decision of every federal agency must "cogently explain why [the agency] has exercised its discretion in a given manner" and "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.").

3. This attorney requested clarification of the following sentence (Paper of 9/9/2005, page 5, lines 1-3): "Contrary to the citations of case law presented by Petitioner, it cannot be seen how [an examiner's] ... 'new line of reasoning' (*In re Kronig*) or 'relying on a new portion of a reference' (*In re Wiechert*)" can be a "new ground of rejection" in the circumstances of this application. T.C. Director Harvey confirmed that that the definition of "new ground" that he applied turned solely on statutory section and choice of references. This attorney asked T.C. Director Harvey if he was aware of any written authority that supported this definition of "new ground of rejection," or that created any exception to the principles of *Kronig* or *Wiechert* quoted in the paper of 9/9/2005. T.C. Director Harvey stated that he did not.

4. T.C. Director Harvey explained as follows (this is a direct transcript of a recording made with the knowledge of T.C. Director Harvey). Note that T.C. Director Harvey states that he will rely solely on the MPEP, even though the MPEP lacks force of law to overrule court or agency precedent. T.C. Director Harvey states that "the Board cases and CCPA cases and Federal Circuit cases on defining 'new ground of rejection'" would not be "helpful" and would not be "taken further." T.C. Director Harvey stated that he would leave all legal research and determinations to other authorities in the PTO.

DB I've cited a couple of CCPA cases that's say that the definition of new ground of rejection looks a little deeper than "same statute, same references." I have looked all over for any written statement that ["same statute, same references" is] the definition of new ground rejection. I don't think there is a written statement to that effect. So, it would just clarify things a whole -- or cut this issue right down to the bone. If you can find the statement to that effect, then if I'm wrong.

JH I have to issue this petition again, and I told you I would do that, and I will sign it, and if it is something I can pull up... It's going to be whatever I

find out of the MPEP. So, it will be my search on the MPEP. I will put it in there. It's going to be a new decision.

DB I think that's fine. And would it make sense for me to send you my legal research?

JH No. We are going to keep it on point. I am not going to take this any further. You have asked me to look up what is the definition of "new ground of rejection" I will do that. We are going to remail out this [decision].

DB You are sure it wouldn't be helpful to look at the Board cases and CCPA cases and Federal Circuit cases on defining "new ground of rejection."

JH No. I am going to leave that to the petitions office when you file that petition.

5. T.C. Director's reissued paper of 11/8/2005 does not reflect that T.C. Director Harvey carried out his promise to "look up what is the definition of 'new ground of rejection.'" The reissued paper of 11/8/2005 does not reflect consideration of MPEP § 1207.03(III) (8th Ed. Rev. 3, August 2005), which expressly defers to the *Kronig* line of case law for the definition of the term "new ground." *See also* MPEP § 1208.01 (7th Ed. and 8th Ed. Jul. 1998-May 2004) (likewise deferring to *Kronig*).

6. Nonetheless, to assist T. C. Director in properly addressing all issues in his "new decision," this attorney filed a "Supplement to Petition" dated 10/31/2005, FAXed directly to SPrE Brian Johnson, and sent the attached email of 11/1/2005 to T.C. Director Harvey and to SPrE Johnson. I certify that the written copy of the email provided with this interview summary is accurate, with the addition of legal annotations, and omission of discussion of statements that T.C. Director Harvey indicated to be "off the record."

7. Applicant offers the following observations of law. Each reinforces the principle that an agency does not have authority to pick and choose which issues it will decide, to ignore grounds when multiple grounds of relief are presented, or to re-characterize the issues presented. The agency must decide the precise matter "presented to it," and each alternative ground. Applicant also comments on the T.C. Director's paper of 11/8/2005.

- 5 U.S.C. § 555(a) ("With due regard for the ... necessity of the parties ... and within a reasonable time, each agency shall proceed to conclude a matter presented to it.")
- *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1052 (Fed. Cir. 2005) ("In accordance with the Administrative Procedure Act, the agency must assure that an applicant's petition is fully and fairly treated at the administrative level...").

It is believed that this paper occasions no fee. Please charge any fee to Deposit Account No. 23-2405, Order No. 114596-03-4000.

Respectfully submitted,

WILLKIE FARR & GALLAGHER LLP

Dated: November 28, 2005

By: _____

David E. Boundy
Registration No. 36,461

WILLKIE FARR & GALLAGHER LLP
787 Seventh Ave.
New York, New York 10019
(212) 728-8000
(212) 728-8111 Fax

Attachment C

Reply to FOIA Request

UNITED STATES PATENT AND TRADEMARK OFFICE

GENERAL COUNSEL

MAR 14 2006

Mr. David Boundy
Willkie Farr & Gallagher
787 Seventh Ave.
New York, NY 10021

Re: Freedom of Information Act (FOIA) Request No. 06-146

Dear Mr. Boundy:

The Office of the General Counsel has received your e-mail dated February 19, 2006, in which you requested, under the provisions of the Freedom of Information Act, 5 U.S.C. § 552, a copy of:

"(1) Attached are two documents I obtained from PTO some time ago. If updated editions of these documents exist, please send them;

(2) Both documents noted in request 1 state that they omit a substantial number of cases. For example, in the one-page table, about 20% of Appeal Briefs filed in the left column are not accounted for in the remaining columns. The large set of tables notes that 'Ex Parte Quayle actions and miscellaneous actions are not included.' What happened to these appeals? In particular, is there any statistic kept relating to which of these appeals end with an acknowledgement that the examiner was wrong and which relate to errors by the appellant?;

(3) Please send any statistics gathered relative to the Pre-Appeal Brief Conference Program; and

(4) I would like any other documents that show the rate of various dispositions of patent appeals within the examining operation, before the file is transferred to the Board of Appeals."

As a preliminary matter, it appears some parts of your FOIA request seek answers to questions or explanatory information regarding released documentation. The FOIA deals in the disclosure and nondisclosure of records only. It does not require agencies to answer questions, provide exegeses or other explanatory addenda. In future FOIA submissions, please limit the requests to specific records only. Failure to do so may result in a rejection of the request as improper.

The United States Patent and Trademark Office identified 10 pages of records that are responsive to Items (1) and (2) of your request. There are no records responsive to items (3) and (4).

Since the cost of processing this request did not exceed $20.00, the applicable fees are waived. See 37 C.F.R. § 102.11(d)(4).

The "no records" determination constitutes a denial of your request for records under the FOIA. The undersigned is the denying official. You have the right to appeal this initial decision to the Deputy General Counsel, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. An appeal must be received within 30 calendar days from the date of this letter. See 37 C.F.R. § 102.10(a). The appeal must be in writing. You must include a copy of your original request, this letter, and a statement of the reasons why the information should be made available and why this initial denial is in error. Both the letter and the envelope must be clearly marked "Freedom of Information Appeal."

Sincerely,

Michael Briskin
FOIA Officer

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 98 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	837	829	409	49.3%	134	16.2%	265	32.0%	21	2.5%
1700	1,558	1,546	902	58.3%	187	12.1%	437	28.3%	20	1.3%
1900	10	10	1	10.0%	0	0.0%	9	90.0%	0	0.0%
2100	417	412	217	52.7%	41	10.0%	150	36.4%	4	1.0%
2600	650	643	408	63.5%	67	10.4%	163	25.3%	5	0.8%
2800	878	870	475	54.6%	130	14.9%	261	30.0%	5	0.6%
3600	525	518	374	72.2%	53	10.2%	84	16.2%	7	1.4%
3700	734	720	449	62.4%	86	11.9%	171	23.8%	14	1.9%
Corps Subtotal	5,609	5,548	3,235	58.3%	698	12.6%	1,540	27.8%	76	1.4%
2900	86	86	62	72.1%	4	4.7%	18	20.9%	2	2.3%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 99 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	823	805	388	48.2%	168	20.9%	231	28.7%	18	2.2%
1700	1,380	1,364	745	54.6%	145	10.6%	461	33.8%	13	1.0%
1900	3	3	0	0.0%	0	0.0%	3	100.0%	0	0.0%
2100	447	444	193	43.5%	91	20.5%	157	35.4%	4	0.9%
2600	649	648	349	53.9%	96	14.8%	197	30.4%	6	0.9%
2800	865	860	431	50.1%	136	15.8%	289	33.6%	5	0.6%
3600	587	572	356	62.2%	81	14.2%	127	22.2%	8	1.4%
3700	746	736	400	54.3%	108	14.7%	208	28.3%	20	2.7%
Corps Subtotal	5,500	5,432	2,862	52.7%	825	15.2%	1,673	30.8%	74	1.4%
2900	53	52	38	73.1%	6	11.5%	9	17.3%	0	0.0%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 00 -- **Updated in March, 2006**

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	732	725	354	48.8%	149	20.6%	197	27.2%	25	3.4%
1700	1,374	1,358	599	44.1%	231	17.0%	510	37.6%	18	1.3%
1900	0	0	0	0.0%	0	0.0%	0	0.0%	0	0.0%
2100	594	593	243	41.0%	161	27.2%	185	31.2%	5	0.8%
2600	816	807	392	48.6%	191	23.7%	212	26.3%	12	1.5%
2800	988	982	456	46.4%	216	22.0%	305	31.1%	5	0.5%
3600	655	645	341	52.9%	132	20.5%	164	25.4%	8	1.2%
3700	775	763	373	48.9%	134	17.6%	240	31.5%	16	2.1%
Corps Subtotal	5,934	5,873	2,758	47.0%	1,214	20.7%	1,813	30.9%	89	1.5%
2900	46	45	26	57.8%	7	15.6%	13	28.9%	0	0.0%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 01 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	844	833	366	43.9%	212	25.5%	239	28.7%	16	1.9%
1700	1,365	1,352	562	41.6%	278	20.6%	495	36.6%	17	1.3%
2100	700	696	282	40.5%	167	24.0%	238	34.2%	9	1.3%
2600	959	950	384	40.4%	285	30.0%	278	29.3%	4	0.4%
2800	1,129	1,128	296	26.2%	325	28.8%	499	44.2%	9	0.8%
3600	762	742	357	48.1%	181	24.4%	188	25.3%	16	2.2%
3700	947	932	460	49.4%	203	21.8%	258	27.7%	12	1.3%
Corps Subtotal	6,706	6,633	2,707	40.8%	1,651	24.9%	2,195	33.1%	83	1.3%
2900	39	38	20	52.6%	2	5.3%	14	36.8%	2	5.3%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 02 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	1,004	982	399	40.6%	281	28.6%	287	29.2%	15	1.5%
1700	1,334	1,317	523	39.7%	313	23.8%	474	36.0%	8	0.6%
2100	629	622	286	46.0%	152	24.4%	180	28.9%	4	0.6%
2600	883	873	312	35.7%	277	31.7%	282	32.3%	2	0.2%
2800	1,267	1,258	280	22.3%	348	27.7%	615	48.9%	15	1.2%
3600	955	919	445	48.4%	281	30.6%	187	20.3%	6	0.7%
3700	929	914	464	50.8%	203	22.2%	239	26.1%	8	0.9%
Corps Subtotal	7,001	6,885	2,709	39.3%	1,855	26.9%	2,264	32.9%	58	0.8%
2900	40	40	31	77.5%	5	12.5%	3	7.5%	1	2.5%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

FY 03 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	1,044	1,013	459	45.3%	296	29.2%	248	24.5%	10	1.0%
1700	1,365	1,355	550	40.6%	344	25.4%	456	33.7%	5	0.4%
2100	1,049	1,045	373	35.7%	336	32.2%	329	31.5%	7	0.7%
2600	992	966	339	35.1%	351	36.3%	274	28.4%	2	0.2%
2800	1,425	1,411	363	25.7%	448	31.8%	594	42.1%	6	0.4%
3600	1,297	1,262	664	52.6%	363	28.8%	225	17.8%	10	0.8%
3700	1,117	1,089	500	45.9%	281	25.8%	298	27.4%	12	1.1%
Corps Subtotal	8,289	8,141	3,248	39.9%	2,419	29.7%	2,424	29.8%	52	0.6%
2900	35	34	20	58.8%	2	5.9%	5	14.7%	7	20.6%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

FY 04 -- Updated in March, 2006

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	987	924	520	56.3%	244	26.4%	150	16.2%	10	1.1%
1700	1,270	1,238	607	49.0%	294	23.7%	320	25.8%	17	1.4%
2100	1,616	1,564	450	28.8%	565	36.1%	540	34.5%	9	0.6%
2600	1,327	1,293	412	31.9%	497	38.4%	378	29.2%	6	0.5%
2800	1,480	1,452	407	28.0%	485	33.4%	546	37.6%	14	1.0%
3600	1,663	1,585	799	50.4%	568	35.8%	203	12.8%	16	1.0%
3700	1,127	1,070	481	45.0%	316	29.5%	257	24.0%	16	1.5%
Corps Subtotal	9,470	9,126	3,676	40.3%	2,969	32.5%	2,394	26.2%	88	1.0%
2900	43	29	23	79.3%	2	6.9%	3	10.3%	1	3.4%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

FY 05 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	1,010	863	457	53.0%	217	25.1%	181	21.0%	9	1.0%

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

1700	1,578	1,426	828	58.1%	380	26.6%	206	14.4%	12	0.8%
2100	2,243	1,990	555	27.9%	905	45.5%	518	26.0%	12	0.6%
2600	1,303	1,136	348	30.6%	443	39.0%	341	30.0%	6	0.5%
2800	1,533	1,369	465	34.0%	470	34.3%	414	30.2%	20	1.5%
3600	2,259	1,804	903	50.1%	641	35.5%	239	13.2%	22	1.2%
3700	1,337	1,138	564	49.6%	314	27.6%	248	21.8%	12	1.1%
Corps Subtotal	11,263	9,726	4,120	42.4%	3,370	34.6%	2,147	22.1%	93	1.0%
2900	26	20	12	60.0%	0	0.0%	8	40.0%	0	0.0%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

FY 06 -- Updated in March, 2006

TC	Appeal Briefs	# of Examiner Actions in Response to Brief	Examiner's Answers	Examiner's Answers / Examiner's Actions	Reopen Prosecution	Reopens / Examiner's Actions	Allowances	Allowances / Examiner's Actions	Other Actions	Other Actions / Examiner's Actions
1600	563	142	83	58.5%	29	20.4%	24	16.9%	6	4.2%
1700	857	343	221	64.4%	83	24.2%	33	9.6%	6	1.7%
2100	1,360	466	151	32.4%	205	44.0%	107	23.0%	3	0.6%
2600	800	311	99	31.8%	118	37.9%	89	28.6%	5	1.6%
2800	705	274	107	39.1%	94	34.3%	73	26.6%	0	0.0%

Appeal Conference Effects - Examiner Actions in Response to Appeal Brief

3600	1,152	351	208	59.3%	102	29.1%	29	8.3%	12	3.4%
3700	618	205	125	61.0%	46	22.4%	34	16.6%	0	0.0%
Corps Subtotal	6,055	2,092	994	47.5%	677	32.4%	389	18.6%	32	1.5%
2900	13	1	1	100.0%	0	0.0%	0	0.0%	0	0.0%

Ex parte Quayle and miscellaneous actions are NOT included in the "Reopens" column above, but are instead included in the "Other Actions" column.

Allowances after Appeal Brief with no BPAI Action

Allowances after Notice of Appeal with No Other Appeal Action

Relationships between Allowances and Either Appeal Briefs or Notices of Appeal

	All UPR Allowances	All UPR Appeal Briefs (AP.B) *	Allowed in FY with Earlier Appeal Brief **	Allowed in FY with Earlier AP.B and no BPAI Action ***	% of Those Allowed with Earlier AP.B and No BPAI Action (E / D)	All UPR Notices of Appeal (N/AP) ****	Allowed in FY with Earlier N/AP *****	Allowed in FY with Earlier N/AP and no AP.B ******
FY 95	107,380	7,037	2,887	1,437	49.77%	15,740	5,291	2,592
FY 96	121,584	6,963	2,942	1,646	55.95%	15,461	5,577	2,928
FY 97	136,188	6,505	3,011	1,767	58.68%	16,210	6,069	3,342
FY 98	143,999	5,612	3,685	1,998	54.22%	15,266	6,827	3,458
FY 99	155,296	5,504	4,351	2,095	48.15%	13,844	7,004	3,040
FY 00	166,113	5,935	5,003	2,331	46.59%	14,829	7,517	3,016
FY 01	167,675	6,704	5,919	2,925	49.42%	16,281	8,457	3,143
FY 02	175,620	6,998	5,671	2,888	50.93%	15,735	8,078	2,932
FY 03	187,658	8,281	5,808	3,223	55.49%	16,545	7,843	2,680
FY 04	176,695	9,403	5,325	3,045	57.18%	17,579	7,300	2,529
FY 05	165,349	10,755	5,221	3,062	58.65%	18,112	6,761	2,203

Allowance numbers above are ***not*** from any annual report.

OPAE reference -- Spar Allow - Brief Data.gwf in Regularly Updated Rports

* Original Appeal Briefs Only = AP.B content entry

** If a CPA, RCE, R129 or another allowance is detected between the target allowance and the appeal brief, the occurrence is NOT counted.

*** If a CPA, RCE, R129, another allowance or a BPAI decision (remands not included) is detected between the target allowance and the appeal brief, the occurrence is NOT counted.

**** Notice of appeal = N/AP content entry

***** If a CPA, RCE, R129 or another allowance is detected between the target allowance and the notice of appeal, the occurrence is NOT counted.

****** If a CPA, RCE, R129, another allowance, a BPAI decision (remands not included) or an appeal brief is detected between the target allowance and the notice of appeal, the occurrence is NOT counted.

FYs 2004 - 2005 updated October 11, 2005

Attachment D

Spreadsheet Combining PTO's Appeal Statistics

Attachment D

Appeal Conference (as of March 2006)

Year	Appeal Briefs	Examiner Actions	Examiner Writes Exr's Answer		Exr Reopens on New Ground (37 CFR § 1.193(b)), usually abandoning existing position		Allowance - all rejn's wrong		Other	
1998	5,609	5,548	3,235	58.3%	698	12.6%	1,540	27.8%	76	1.4%
1999	5,500	5,432	2,862	52.7%	825	15.2%	1,673	30.8%	74	1.4%
2000	5,934	5,873	2,758	47.0%	1,214	20.7%	1,813	30.9%	89	1.5%
2001	6,706	6,633	2,707	40.8%	1,651	24.9%	2,195	33.1%	83	1.3%
2002	7,001	6,885	2,709	39.3%	1,855	26.9%	2,264	32.9%	58	0.8%
2003	8,289	8,141	3,248	39.9%	2,419	29.7%	2,424	29.8%	52	0.6%
2004	9,470	9,126	3,676	40.3%	2,969	32.5%	2,394	26.2%	88	1.0%
2005	11,263	9,726	4,120	42.4%	3,370	34.6%	2,147	22.1%	93	1.0%
2006[19]	6,055	2,092	994	47.5%	677	32.4%	389	18.6%	32	1.5%

Board of Patent Appeals (as of Sept 27, 2007)

Year	Total Dispos'ns	Affirmed		Modified / Aff'd in Part, Rev'd in Part		Reversed in full		Remanded (combining "panel" and "administrative")		Dismissed		Withdrawn		Total Net Affirmance (end to end)
1998	4,091	1,464	35.8%	391	9.6%	1,239	30.3%			69	1.7%	70	1.7%	**24%**
1999	4,520	1,283	28.4%	504	11.2%	1,573	34.8%	986	21.8%	169	3.7%	5	0.1%	**18%**
2000	4,963	1,442	29.1%	518	10.4%	1,930	38.9%	911	18.4%	152	3.1%	10	0.2%	**16%**
2001	5,075	1,516	29.9%	459	9.0%	1,868	36.8%	1,089	21.5%	143	2.8%	0	0.0%	**14%**
2002	5,062	1,509	29.8%	471	9.3%	1,895	37.4%	1,095	21.6%	92	1.8%	0	0.0%	**14%**
2003	3,815	1,398	36.6%	413	10.8%	1,490	39.1%	453	11.9%	61	1.6%	0	0.0%	**17%**
2004	3,436	1,276	37.1%	401	11.7%	1,282	37.3%	397	11.6%	80	2.3%	0	0.0%	**17%**
2005	2,937	1,121	38.2%	366	12.5%	1,163	39.6%	176	6.0%	111	3.8%	0	0.0%	**19%**
2006	2,874	1,256	43.7%	348	12.1%	1,001	34.8%	179	6.2%	90	3.1%			**24%**

[19] The rise in affirmance rate for FY 2006 may be due to the "Pre-Appeal Review" program. The number of rejections vacated and reversed in this program are not reflected in the statistics presented. Thus, the FY 2006 statistics overstate the number of affirmance.

Attachment E

Draft “Restatement of the Law of Appeals Jurisdiction” for MPEP § 1201

Attachment E

Draft "Restatement of the Law of Intra-PTO Jurisdiction" for inclusion in MPEP § 1201

The United States Patent and Trademark Office (Office) in administering the Patent Laws makes many decisions of a substantive nature which the applicant may feel deny him or her the patent protection to which he or she is entitled. The differences of opinion on such matters can be justly resolved only by prescribing and following judicial procedures. Where the differences of opinion concern the denial of patent claims because of prior art or other patentability issues, the questions thereby raised are said to relate to the merits, and appeal procedure within the Office and to the courts has long been provided by statute (35 U.S.C. § 134). Where the differences opinion lie between the examiner and mandatory instructions issued pursuant to supervisory obligations of the Director of the U.S. Patent and Trademark Office (Director) and Commissioner for Patents (Commissioner), or the procedural rulemaking authority of the Office, relief by petition is provided by rule (37 C.F.R. § 1.181).[20]

The line of demarcation between appealable matters for the Board of Patent Appeals and Interferences (Board) and petitionable matters for the Director ~~of the U.S. Patent and Trademark Office (Director)~~ should be carefully observed. The Board will not ordinarily hear a question that should be decided by the Director on petition, and the Director will not ordinarily entertain a petition where the question presented is a matter appealable to the Board. On appeal, the Board reviews only "adverse decisions of examiners upon applications for patents." 35 U.S.C. § 6(b), § 134(a). This has two important implications, first that appealable issues relate to "rejections," second, that only "decisions" are appealable. Both of these are explained further below.

~~However, since~~ Since 37 C.F.R. § 1.181(f) states that any petition not filed within 2 months from the action complained of may be dismissed as untimely and since 37 C.F.R. § 1.144 states that petitions from restriction requirements must be filed no later than appeal, petitionable matters will rarely be present in a case by the time it is before the Board for a decision. *In re Watkinson*, 900 F.2d 230, 14 USPQ2d 1407 (Fed. Cir. 1990).

This chapter is primarily directed to *ex parte* appeals. For appeals in *inter partes* reexamination proceedings, see 37 C.F.R. §§ 41.60 to 41.81 and MPEP §§ 2674 to 2683.

A. "Rejection" is a Necessary But Not Sufficient Condition For Appealability

The Board cannot have jurisdiction over issues where there is no rejection of claims. For example, in *In re Volk*, 634 F.2d 607, 609-10, 207 USPQ 1086, 1087-88 (CCPA 1980), the appellant objected to the claim construction that had been applied to the claims in determining that the claims were patentable. The court held that because there was no rejection, there was no jurisdiction.

---

[20] If the Office ever had authority to decline to enforce its internal guidance, that authority was revoked by the President in January 2007. See footnote 10.

The mere label "rejection" vs. something else is not determinative of the Board's jurisdiction, in either direction. For example, an apparently-procedural limit may be so restrictive that no claim of a given scope could ever be examined, let alone issued, even though not denominated a "rejection." Such *de facto* rejections are appealable. *In re Haas*, 486 F.2d 1053, 1056, 179 USPQ 623, 625 (CCPA 1973) (labeling a requirement "rejection" or not cannot be determinative of jurisdiction; when prosecution of claims is closed such that "[the claims] were never to be considered on the bases of § 102, § 103 and § 112" then a requirement not phrased as a rejection may nonetheless be appealable).

Similarly, the mere label "reject" does not create jurisdiction in the Board, as discussed in sections (B), (C) and (D).

B. The Board Only Has Jurisdiction to Review "Decisions" of Ultimate Statutory Patentability, not Underlying Reasons or Issues of Examination Procedure

Appeal to the Board is from a "decision" of the examiner, not from the reasons upon which such decision is based. 35 U.S.C. § 6(b), § 134(a); 37 C.F.R. § 41.31(a); *Ex parte Maas*, 14 USPQ2d 1762, 1764 (BPAI 1987); *see also* 37 C.F.R. § 41.50(a)(1) ("The Board, in its decision, may affirm or reverse the decision of the examiner in whole or in part on the grounds and the claims specified by the examiner."); *In re Priest*, 582 F.2d 33, 37, 199 USPQ 11, 14 (CCPA 1978) (rejecting the PTO's argument that "opinions" merge with "decisions" for review, holding that an "opinion" is almost always distinct from a "decision," and only the single sentence "decision" is reviewable by the Board, with only "narrowly defined" exceptions). [21]

In this respect, the Board's review of an examiner is more like court/court review (where an appellate court reviews only the decision, not the reasoning, and may affirm on other grounds) than like court/agency review (where an agency may be affirmed, if at all, only on grounds that the agency itself has expressed, after a "searching and careful" inquiry into that reasoning.[22]).

C. The Board has Supplemental Jurisdiction over Many but Not All Issues Underlying Ultimate Decisions of Non-Patentability

Decisions of patentability involve underlying issues, most of which are reviewable by the Board as part of the review of the ultimate decision.

The Board applies a *de novo* standard of review to examiners' determinations of claim interpretation under a "broadest reasonable interpretation consistent with the specification" standard of interpretation.

The Board reviews examiners' assertions of fact with no deference. All elements of all *prima facie* elements of all grounds of rejection by either the Board or the examiner must be supported by "substantial evidence." 5 U.S.C. § 706(2)(E); *Universal Camera Corp. v. Nat' Labor Relations Bd.*, 340 U.S. 474, 487-88 (1951); *In re Gartside*, 203 F.3d 1305, 1312, 53 USPQ2d 1769, 1773 (Fed. Cir. 2000). "Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. Agencies such as the PTO may not rely on "irresponsible admission and weighing of hearsay, opinion, and emotional speculation in place of factual evidence" or "'suspicion, surmise, implications, or plainly incredible

---

[21] *Ex parte Miller*, 1995 WL 1768479 (BPAI 1995) ("We review the decision, not the reasoning…").

[22] *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

evidence." *Universal Camera*, 340 U.S. at 478, 484, 488. Only if this evidentiary burden is met for all *prima facie* elements does the burden of coming forward with rebuttal argument or evidence shift to the applicant. The Board must review the factual sufficiency of the examiner's decision (either based solely on the *prima facie* case or on the evidence in the record as a whole, if the applicant has rebutted) on a preponderance of evidence. On further judicial review, the Board's decisions on issues of fact will be reviewed on a "substantial evidence" standard, so appellants are well advised to come forward with rebuttal evidence before appeal.

Issues of law are reviewed *de novo*. Decisions of the Court of Appeals for the Federal Circuit or its predecessor, the Court of Customs and Patent Appeals, are normally considered as binding precedent on the Board. *Ex parte McGrew*, 41 USPQ2d 2004, 2007 (BPAI 1995), *aff'd sub nom. In re McGrew*, 43 USPQ2d 1632 (Fed. Cir. 1997), *Ex parte Holt*, 19 USPQ2d 1211, 1214 (BPAI 1991); Standard Operating Procedure No. 2 (revision 6, Aug. 10, 2005) § VI, http://www.uspto.gov/ web/offices/dcom/bpai/sop2.pdf.

When primary jurisdiction for an issue lies either with the Board or with the Director by Petition, in a few cases the other may have concurrent or supplemental jurisdiction to review the identical issue. These are primarily issues that are ordinarily reviewable by petition, but that may be reviewed on appeal when bound up in a rejection and that "require the exercise of legal judgment:"

a) "New interpretations of law" in an Examiner's Answer are subject to concurrent petitions jurisdiction, MPEP § 1003 ¶ 10 (reviewable by T.C. Director), or an applicant may obtain the Board's adjudication of such questions of law.

b) Whether a final decision of the Board introduces a "new ground of rejection" that triggers the procedural protections of 37 C.F.R. § 1.196(b). *In re Oku*, 25 USPQ2d 1155, 1157 (Comm'r Pats. & TM 1992)(stating the issue is primarily appealable, but within supplemental petitions jurisdiction when it "involves the important question of whether [a PTO employee] followed PTO regulations established by the Commissioner" and when the relief requested is solely within the jurisdiction of the Commissioner).

c) Obtaining an earlier filing date to antedate prior art. MPEP § 1002.02(b) (petitionable); *In re Makari*, 708 F.2d 709, 711, 218 USPQ 193, 194 (Fed. Cir. 1983) (appealable).

d) The correctness of a restriction requirement between species of a Markush group. *In re Weber*, 580 F.2d 455, 458, 198 USPQ 328, 332 (CCPA 1978) (appealable); 37 C.F.R. § 1.113(a) (petitionable).

e) Consideration of an affidavit to overcome a rejection. MPEP § 1002.02(c)(3)(d) (petitionable); *In re Searles*, 422 F.2d 431, 435, 164 USPQ 623, 626 (CCPA 1970) (primary jurisdiction over the examiner's decision was exclusively by petition, but the Board had supplemental jurisdiction when the issue was "determinative of a rejection" and review "required the exercise of technical skill and legal judgment").

This concurrent jurisdiction may persist in one tribunal even after adjudication by the other. *E.g.*, *Searles*, 422 F.2d at 435, 164 USPQ at 626; *Oku*, 25 USPQ2d at 1157.

The Board does not have jurisdiction over the following issues:

f) Premature final rejection, MPEP § 706.07(c).

g) Issues arising under sources of law other than the substantive patent law, 35 U.S.C. §§ 101, 102, 103, 112, and 135(b) and similar statutes. The Board only has jurisdiction to determine whether a patent may lawfully be granted on the claims

presented.[23] Issues of proper examination procedure arising under other law, such as 35 U.S.C. §§ 131 and 132 (a renewed rejection must state "reasons"), 37 C.F.R. §§ 1.104 and 1.113, the Manual of Patent Examining Procedure[24] (including requirements that the examiner address all elements of *prima facie* unpatentability), the Administrative Procedure Act[25], constitutional procedural guarantees[26], and similar procedural law are generally not within the Board's jurisdiction.

h) Questions regarding the conduct of an examiner in abusive rejections of claims are petitionable rather than appealable.[27] Supervision of examiners – including examiners' rejection of claims – is committed by statute to the Director and Commissioner of Patents, 35 U.S.C. § 131 ("the Director shall cause an examination to be made…"); 35 U.S.C. § 3(b)(2)(A) (Commissioner for Patents is responsible "for the management and direction of all aspects of the activities of the Office that affect the administration of patent . . . operations."), not the Board.

D. Available Relief and Supervisory Authority of the Board

An issue is not appealable when the Board lacks power to grant the relief requested.[28]

---

[23] *Ex parte Vander Wal*, 109 USPQ 119, 123 (1955).

[24] *Sehgal v. Revel*, 81 USPQ2d 1181, 1186-87 (BPAI 2005) (MPEP is "directed to patent examiners conducting normal examination," not to the Board); *Ex parte Haas*, 175 USPQ 217, 220 (Bd. Pat. App. 1972) (*Haas I*) ("If the examiner fails to follow the Commissioner's directions in the M.P.E.P., appellant's remedy is by way of petition to the Commissioner since this Board has no jurisdiction over the examiner's action.") (Lidoff, EIC, concurring), *rev'd on other grounds*, 486 F.2d 1053, 179 USPQ 623 (CCPA 1973) (*Haas II*). The Board's Standard Operating Procedure No. 2 (revision 6, Aug. 10, 2005) § VI, lists the authority by which the Board considers itself bound. The MPEP is not even on the list. Similarly, in *Ex parte Holt*, 19 USPQ2d 1211, 1214 (Bd. Pat. App. & Interf. 1991), the MPEP is absent from the list of precedent by which the Board considers itself bound.

[25] *See In re Wiechert*, 370 F.2d 927, 938, 152 USPQ 247, 255 (CCPA 1967) (jurisdiction for APA review lies with district court, not the Board).

[26] *See Ex parte Kimbell*, 226 USPQ 688, 690 (BPAI 1985) (Board does not have jurisdiction to evaluate constitutionality of statutes, breaches of due process, or alleged harassment by examiner).

[27] *Ex parte Global Patent Holdings LLC, U.S. Pat. No. 5,235,341*, Appeal No. 2006-0698, http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&flNm=fd2006069812-26-2006, at p. 9 (BPAI Dec. 26, 2006).

[28] A particular set of facts may give rise to rights to different kinds of relief, and different claims for relief on the same facts may have different jurisdictional paths. *E.g.*, *Federal Communications Comm'n v. NextWave Personal Communications Inc.*, 537 U.S. 293, 302-03 (2001) (same facts gave rise to New York bankruptcy action and D.C. Administrative Procedure Act action, and decision in favor of agency in one court did not preclude discharge of debt in the other). An agency may not require that an issue be presented to a tribunal that has no power to grant the type of relief requested. *McCarthy v. Madigan*, 503 U.S. 140, 148 (1992); *Maggitt v. West*¸ 202 F.3d 1370, 1377 (Fed. Cir. 2000). Thus, issues of examiner non-compliance with

The relief available in an appeal to the Board is a reversal of rejections. A reversal is not a declaration of patentability; it is only a reversal on the issues then pending. The examiner has authority to re-open prosecution on different issues, though under narrow limits prescribed by the Director. *See*, *e.g.*, MPEP § 1214.04; *see also Blacklight Power Inc. v. Rogan*, 295 F.3d 1269, 1273-74, 63 USPQ2d 1534, 1537 (Fed. Cir. 2002) (PTO may withdraw a patent from issue, but only after it fully presents a *prima facie* case of unpatentability).

The Board may also remand an application to the examiner, 37 C.F.R. § 41.50(a)(1), but only when the parties have not provided the Board with sufficient information to make a final adjudication. 5 U.S.C. § 555 (agency appellate tribunals are required "within a reasonable time, … to conclude a matter presented to it," and may not "bounce" matters to lower-level adjudicators when the information necessary to reach a final decision is available).[29] The Board does not have authority to issue mandatory supervisory instructions in a remand order.[30] For a non-exhaustive list of bases for remand, see MPEP § 1211.

The Board's jurisdictional statutes (35 U.S.C. §§ 6 and 134) do not charge the Board with supervision of the patent examining operation. The Board does not exercise supervisory authority over examiners,[30] and has no management power over the examining corps. In examining claims under §§ 131 and 132, an examiner acts as an agent of the Director, not of the Board. Statements framed in mandatory language in the MPEP or Code of Federal Regulations are binding on examiners and enforceable by the examiner's supervisory chain. Executive Order 13,422; Executive Office of the President, Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007).[31] Thus, actions of an examiner that violate written mandatory language in the MPEP or 37 C.F.R.

PTO procedural rules are not appealable as stand-alone issues (and only rarely within the Board's supplemental jurisdiction), only the ultimate rejection.

[29] *British Airways Board v. Port Authority of New York and New Jersey*, 564 F.2d 1002, 1012 (2d Cir. 1977) (an agency must pursue some path that will "resolve those issues in the reasonably foreseeable future."); *Deering-Milliken Inc. v. Johnston*, 295 F.2d 856, 865 (4th Cir. 1961); *McDonnell Douglas Corp. v. National Aeronautics and Space Admin.*, 895 F.Supp. 316, 319 (D.D.C. 1995) (condemning "second bites" and an agency's "never ending loops")

[30] Even on remand, "The board does not exercise supervisory authority over examiners." Board of Patent Appeals, Frequently Asked Questions page, http://www.uspto.gov/web/offices/ dcom/bpai/bpaifaq.htm, "Answer to Question 8, Part One." This attorney has searched diligently, and in the history of the Board, there appears to be only one instance in which the Board has ever issued a mandatory order to an examiner. Note that the remand cases listed in footnote 34 consistently remand with no mandatory order. The Board's acknowledges that it lacks power to compel an examiner's compliance with any rule on further examination. *E.g.*, *Gambogi*, 62 USPQ2d at 1212 ("We decline to tell an examiner precisely how to set out a rejection"). The Board at most offers non-binding "suggestions," with nothing like the detail set out in the MPEP.

[31] *See also Ethicon Inc. v. Quigg*, 849 F.2d 1422, 1425, 7 USPQ2d 1152, 1154 (Fed. Cir. 1988) ("The MPEP states that it is a reference work on patent practices and procedures and does not have the force of law, but it 'has been held to describe procedures on which the public can rely.'"); *PerSeptive Biosystems Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321, 56 USPQ2d 1001, 1005 (Fed. Cir. 2000) (MPEP sets out "required" actions, and "details the 'rules' … to be used by examiners").

§ 1.104 are outside of the delegation of authority from the Director principal to the examiner agent.[32] These relate to examination procedure rather than ultimate issues of patentability, and the appropriate relief is supervisory oversight, which should be obtained by telephone calls to the examiner's supervisory chain, or by Petition under 37 C.F.R. § 1.181.[33] Supervisory oversight is not within the Board's powers of relief.

Several other forms of relief are solely within the authority of the Commissioner and Director: reopening of prosecution, *In re Oku*, 25 USPQ2d 1155, 1157 (Comm'r Pats. & TM 1992), and withdrawal of premature final rejection, MPEP § 706.07(c). Thus, issues seeking these forms of relief are not appealable.

---

[32] Restatement 2d (Agency), § 33 ("An agent is authorized to do, and to do only, what it is reasonable for him to infer that the principal desires him to do in the light of the principal's manifestations..."); Restatement 2d (Agency) § 214 ("A … principal who is under a duty to … to have care used to protect others or their property and who confides the performance of such duty to a servant or other person is subject to liability to such others for harm caused to them by the failure of such agent to perform the duty.")

[33] The Federal Circuit recently clarified the distinction between merits issues and procedural issues, in a way that clarifies that procedural issues underlying rejections of claims are within the scope of the Director's supervisory obligations: "The scope of APA review is not, as the district court feared, to test the examiner's theory of the case or the examiner's findings of fact. The district court, on APA review, does not enmesh itself in the decision-making process of the examiner. Its function, instead, is simply to guard against the possibility of arbitrary or capricious behavior by examiners in seeking information." *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1285, 73 USPQ2d 1409, 1415 (Fed. Cir. 2005)

Appeals are "manifestly not ready for a decision" and "not ripe"[34] – that is, the Board lacks jurisdiction to render a final decision – where the examiner has omitted findings on an element of the relevant *prima facie* case. The Board cannot efficiently perform its adjudicatory functions unless applicants and examiners, possibly with the assistance of the supervisory authority of the Director and Commissioner, ensure that prosecution and examination are complete before an appeal commences. To ensure appeals are fully ripe, and that a "clear issue for appeal" is developed before appeal, MPEP § 706.07, final rejection and issues of examination procedure should be addressed by telephone conference with the examiner, or the examiner's supervisor, by request for correction pursuant to MPEP § 710.06, or by petition under 37 C.F.R. § 1.181, to clarify the following types of omissions from examiners' actions:

i) complete omission of comparison of one or more claim elements to any reference;

j) mere designation of a "portion" of a reference, without "clear explanation" when required by 37 C.F.R. § 1.104(c)(2);

k) reliance on facts within the personal knowledge of an employee of the Office after timely applicant action as specified in 37 C.F.R. § 1.104(d)(2);

l) omission of discussion of one or more *prima facie* elements as defined in the relevant portions of MPEP Chapters 700 or 2100, or substitution of an unauthorized legal test for a test stated in mandatory terms in the MPEP;

m) failure to answer all material traversed, MPEP § 707.07(f).

Generally, an applicant is entitled to receive some written notice of the examiner's position on each *prima facie* element of non-patentability, and each claim element. It is the responsibility of the Director and Commissioner to ensure that the examiner does not "sit

---

[34] The Board has persistent inability to decide cases because of omissions in the examiner's half of the record. *E.g.*, *Ex parte Daleiden*, Appeal 2007-1003, fd2007100303-14-2007.pdf (Mar. 14, 2007) (remanding because examiner failed to respond to arguments in the Appeal Brief); *Ex parte Rozzi*, 63 USPQ2d 1196, 1200-03 (BPAI 2002) (McKelvey, J.) (remanding without decision because of a host of examiner omissions and procedural errors); *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI 2001) (McKelvey, APJ) ("We decline to tell an examiner precisely how to set out a rejection."); *Ex parte Jones*, 62 USPQ2d 1206, 1208 (BPAI 2001) (McKelvey, APJ) (refusing to adjudicate an issue that the examiner has not developed); *Ex parte Schricker*, 56 USPQ2d 1723, 1725 (BPAI 2000) ("The examiner has left applicant and the board to guess as to the basis of the rejection … We are not good at guessing; hence, we decline to guess."); *Ex parte Braeken*, 54 USPQ2d 1110, 1112-13 (BPAI 1999) (McKelvey, APJ) (noting that the appeal is "not ripe" because of omissions and defects in the examiner's analysis). Other appellate tribunals frequently state that they are unable to review decisions when inferior tribunals have not stated the necessary findings, or otherwise present an undeveloped record. *E.g.*, *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811, 229 USPQ2d 478, 479 (1986) (obviousness has separate "procedural" and "substantive" aspects, and the Supreme Court cannot review the substantive issue when the underlying decision is procedurally incomplete); *Warner-Lambert Co. v. Teva Pharmaceuticals USA, Inc.*, 418 F.3d 1326, 1337-38, 75 USPQ2d 1865, 1872-73 (Fed. Cir. 2005) ("We find the issue of enable difficult to review… We have no way of knowing what the district court thought of Teva's enablement defense or why the court did not address the issue in its decision. In short, we are being asked to review an incomplete record…); *Nazomi Communications Inc v. ARM Holdings Inc.*, 403 F.3d 1364, 1371-73, 74 USPQ2d 1458, 1463-64 (Fed. Cir. 2005) (remanding because of district court's failure to make findings, rendering appellate review impossible)

mum, leaving the applicant to shoot arrows into the dark." *In re Oetiker*, 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) (Plager, J., concurring)[35] However, once those positions are articulated to at least some minimal degree, appeal to the Board is the appropriate resolution of disagreements.

E. Jurisdiction to Determine the Board's Jurisdiction Lies with the Board

Like almost all other statutorily-constituted tribunals, the Board of Patent Appeals and Interferences has jurisdiction to determine its own jurisdiction. *Ex parte Lemoine*, 46 USPQ2d 1432, 1434 (BPAI 1995) and cases cited therein. Decisions regarding the Board's jurisdiction by other portions of the PTO, while worthy of serious consideration, are not, and can not be, binding on the Board. *Lemoine*, 46 USPQ2d at 1434. The Board's jurisdiction does not attach until the examining corps has finished its job and transfers the application file to the Board. The examining operation can not create jurisdiction where none exists. *Lemoine*, 46 USPQ2d at 1434.

[35] *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995) ("The examiner bears the burden of establishing a *prima facie* case of obviousness," emphasis added); *In re Oetiker*, 977 F.2d 1443, 1445-46, 24 USPQ2d 13443, 1444 (Fed. Cir. 1992) ("the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. … If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent … We think that the PTO is correct in treating the concept of the *prima facie* case as of broad applicability, for it places the initial burden on the examiner, the appropriate procedure whatever the technological class of invention" emphasis added).

Attachment F

Draft “Restatement of the Law of ‘New Ground of Rejection’” for inclusion in MPEP

Attachment F

Draft "Restatement of the Law of 'New Ground of Rejection'" for inclusion in MPEP

A definition of the term "new ground of rejection" should be set forth in MPEP § 706.07(a) or § 1207.03. Here is a first draft that may be considered.

> The term "new ground of rejection" is defined as any "position or rationale new to the proceedings," including new evidence, citation to a new portion of existing evidence, a new inference drawn from an existing reference, a new legal theory, or a new application of law to facts.[36] For example, designating a new "particular part relied on" or relying on a "different portion" of a reference is a "new ground of rejection." *In re Wiechert*, 370 F.2d 927, 933, 152 USPQ 247, 251-52 (CCPA 1967) ("An applicant's attention and response are naturally focused on that portion of the reference which is specifically pointed out by the examiner. … [W]hen a rejection is factually based on an entirely different portion of an existing reference the appellant should be afforded an opportunity to make a showing of unobviousness vis-à-vis such portion of the reference").[37] A new reference, even one

---

[36] *In re DeBlauwe*, 736 F.2d 699, 706 n. 9, 222 USPQ 191, 197 n.9 (Fed. Cir. 1984) (interpreting the term "new ground" in 37 C.F.R. § 1.196(b): "Where the board makes a decision advancing a position or rationale new to the proceedings, an applicant must be afforded an opportunity to respond to that position or rationale by submission of contradicting evidence"); *In re Kronig*, 539 F.2d 1300, 1302-03, 190 USPQ 425, 426 (CCPA 1976); *In re Eynde*, 480 F.2d 1364, 1370-71, 178 USPQ 470, 474 (CCPA 1973) ("We do agree with appellants that where the board advances a position or rationale new to the proceedings… the appellant must be afforded an opportunity to respond to that position or rationale by the submission of contradicting evidence. This court so held in *In re Moore*, [444 F.2d 572, 170 USPQ 260 (CCPA 1971)], and we expressly reaffirm that view. The board's refusal to consider evidence which responds to such a new rationale is error."); *Ex parte Teeple*, Appeal No. 97-0943, 1997 WL 1883925 at *2-3, http://www.uspto.gov/go/dcom/bpai/ decisions/fd970943.pdf at 7, 9 (BPAI Feb. 17, 1998) (new explanation for § 112 ¶ 2 rejection of same claim language is "new ground" of rejection); MPEP § 1207.03(III) (8th Ed. Rev. 3, August 2005) (deferring to the *Kronig* line of case law for the definition of the term "new ground"); MPEP § 1208.01 (7th Ed. and 8th Ed. Jul. 1998-May 2004) (likewise deferring to *Kronig*); Final Rule, 62 FR 53132, 53168 (Oct. 10, 1997) (likewise deferring to *Kronig*).

[37] *See also In re Echerd*, 471 F.2d 632, 635, 176 USPQ 321, 323 (CCPA 1973) ("We find the new reliance [to be] a new ground of rejection. New portions of the reference are relied upon to support an entirely new theory… appellants should have been accorded an opportunity to present rebuttal evidence as to the new assumptions of inherent characteristics made by the board"), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427. The PTO's more-recent decisions regularly reinforce this principle. *E.g.*, *Ex parte Kelcher*, Appeal No. 1999-1899, 2002 WL 63644 at *3-4, http://www.uspto.gov/go/dcom/bpai/ decisions/fd991899.pdf at 9-10 (BPAI

offered to back up a previous assertion of official notice, is always a new ground of rejection.[38] A new reference offered to show "level of skill in the art" or "motivation to modify" or "motivation to combine" is a "new ground."[39] A new factual finding or inference, even one drawn from the identical portions of existing references, or a new application of the law to the identical facts, is a "new ground of rejection."[40] A new supporting position or rationale is a "new ground," even if it is simply offered to buttress a previous analysis or inference.[41] A new application of the law to the facts is a "new

---

Feb. 28, 2001) (new reliance on an arrow in a figure of an existing reference is a "new ground of rejection"); *Ex parte D'Andrade*, Appeal No. 1999-1235, 1999 WL 33224326 at *3, …/fd991235.pdf at 7, 10 (BPAI Sep. 30, 1999) (shift from examiner's reliance on tension spring 59 to Board's reliance on tension spring 61 in the same single reference is a "new ground of rejection"); *In re Intine*, 162 USPQ 192, 192 (Comm'r of Patents 1969) (a shift from references A and B to references A, B and C, where C had previously been relied upon, prevented final rejection).

[38] *In re Ahlert*, 424 F.2d 1088, 1092 n. 4, 165 USPQ 418, 421 n. 4 (CCPA 1970) (commenting on a new reference to buttress an assertion of official notice, "it is not uncommon for the board itself to cite new references, in which case a new ground of rejection is always stated," emphasis added); *Ex parte Skinkiss*, Appeal No. 2000-0226, 2002 WL 99652 at *1 n.1, http://www.uspto.gov/go/dcom/bpai/decisions/fd000226.pdf at 4 n. 1 (BPAI June 14, 2001) ("new piece of evidence," even an assertion of "well-known custom," constitutes "a new ground of rejection").

[39] *Ex parte Mathur*, Appeal No. 95-4103, 1996 WL 1795838 at *3-4, 6, http://www.uspto.gov/ go/dcom/bpai/decisions/fd954103.pdf at 7, 9-10, 15-16 (BPAI June 26, 1996) (new references offered by the examiner to support "level of skill in the art" but not directly applied, and relied upon by the Board to support "motivation to combine" the original references, were "new grounds of rejection").

[40] *In re Moore*, 444 F.2d 572, 574-75, 170 USPQ 260, 263 (CCPA 1971) (any new "finding of a new fact," even from the same reference, even solely in support of an alternative to the pre-existing rationale, requires that the applicant be given an opportunity to respond), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427; *see also In re Meyer*, 599 F.2d 1028, 1031, 202 USPQ 175, 179 (CCPA 1979) (holding that the Board's § 102 rejection is a "new ground of rejection" even though based on the same art as the examiner's § 103 rejection).

[41] *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005) (a new calculation applied to a reference is not "simply an additional explanation of the Board's decision," it is a new ground of rejection); *In re Waymouth*, 486 F.2d 1058, 1061, 179 USPQ 627, 629 (CCPA 1973) ("merely advanc[ing] 'an additional reason' for affirming the examiner" is a "new rejection"), *modified* 489 F.2d 1297, 180 USPQ 453 (CCPA 1974), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427; *Moore*, 444 F.2d at 574-75, 170 USPQ at 263, *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427; *Ex parte Lachut*, Appeal No. 2001-0933, 2002 WL 31257834 at *5, http://www.uspto.gov/go/dcom/bpai/decisions/ fd010933.pdf at 9 (BPAI Mar. 14, 2002) (new analysis and inferences drawn from the same portion of Hazen reference is a new point); *Ex parte Hanlon*, Appeal No. 98-2033, 1998 WL 1748535 at *2-3, …/fd982033.pdf (Board's different analysis of the same portion of the same reference is a "new ground of rejection").

ground," if the "basic thrust" differs.[42] A new claim interpretation is a "new ground."[43] Any notion that a "new ground" requires a new reference or shift from one statutory section to another has been expressly rejected by the Federal Circuit, the CCPA, and by the Board, and is inconsistent with the plain language of MPEP § 706.07(a), which treats them as separate but overlapping concepts.[44]

It is important to differentiate between the *substantive* principle that a reference is good for all it contains, whether designated by the examiner or not, and the *procedural* principles underlying compact prosecution and "new grounds of rejection," under which only the portions actually designated as required by 37 C.F.R. § 1.104(c)(2) are relevant.

The Federal Circuit and CCPA have several times declined to create any exception for new grounds raised by an examiner in response to an applicant's arguments – any new "position or rationale new to the proceedings" is a "new ground" that prevents final rejection, or that triggers the "new ground of rejection" options for an appellant during on appeal, even if that new position or rationale is expressed by the PTO in response to a new argument from the applicant.[45] Applicants must be given a fair opportunity to react to the

---

[42] *Ex parte Albrecht*, Appeal No. 2000-0460, 2002 WL 1801026 at *2, http://www.uspto.gov/go/ dcom/bpai/decisions/fd000460.pdf at 4 (BPAI Oct 31, 2001) (vacating the examiner, and ordering him to give the applicant "a full and fair opportunity to respond," because the examiner raised a "new ground of rejection" by shifting emphasis within a group of references, without introducing a new reference); *Ex parte Mattel Inc.*, Appeal No. 1999-2373, 2003 WL 22282332 at *6, *10, …/fd992373.pdf at 13-14, 23-24 (BPAI Oct. 29, 1999) (different analysis of claims 10 and 11, on the same Adachi and Kimura references, is a new ground of rejection); *Ex parte Coe*, Appeal No. 95-4526, 1995 WL 1747721 at *5, …/fd954526.pdf at 13-14, 16 (BPAI May 28, 1998) (a different analysis of the same two references, Sukiennik and Nosaki, of the same claim, claim 4, is a "new ground of rejection").

[43] *Ex parte American Academy of Science*, remand in Appeal No. 1998-1483, App. Ser. No. 90/003,463, http://www.uspto.gov/go/dcom/bpai/decisions/rm981483.pdf (BPAI Feb. 2000).

[44] *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051 (Fed. Cir. 2005); *In re Ahlert*, 424 F.2d 1088, 1098, 165 USPQ 418, 421 (CCPA 1970) (new facts based on an existing reference are a new ground of rejection, even if cast as "official notice"); *In re Bulina*, 362 F.2d 555, 558-59, 150 USPQ 110, 113 (CCPA 1966), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427. The difference cuts both ways – when a new single-reference § 102 rejection is based on the identical portions of one reference from a multi-reference § 103 combination, that shift is not a "new ground."

[45] *In re Kumar*, 418 F.3d 1361, 1367, 76 USPQ2d 1048, 1051-52 (Fed. Cir. 2005) (Board's new analysis of the identical disclosure, by calculating new derived values from those expressly disclosed in the reference, was a "new ground"); *In re DeBlauwe*, 736 F.2d 699, 705-06, 222 USPQ 191, 196-197 (Fed. Cir. 1984) (when an applicant has argued a point, the examiner and Board are obligated to respond to those arguments, and their new response requires giving an applicant a new opportunity to respond):

> … Appellants complain, however, that the PTO challenges their assertions of unexpected results for the first time in the Solicitor's brief. …
>
> Despite appellants' arguments throughout prosecution that heat shrinkable articles with the claimed expansion ratios overcome the longstanding splitting problem, the board and the examiner merely concluded that these ratios would have been obvious without properly responding to appellants' allegations of

thrust of any new ground, *Kronig*, 539 F.2d at 1303, 190 USPQ at 426, regardless of the time or context in which the examiner's "new position or rationale" arises. For example, if the new ground is introduced in response to an applicant's showing that an old ground of rejection is weak or untenable, any shift or buttressing is still a "new ground," and the applicant must be given full opportunity to reply.[46]

An examiner's silence in an earlier paper can lead to a finding of a "new ground of rejection" if subsequent events make relevant any reply that an applicant would have raised had the examiner not been silent.[47]

---

unexpected results. … if the board or the examiner had considered this point when the case was pending before them and had pointed out that there was no objective evidence of unexpected results, appellants would, at least, have had notice and would have had an opportunity to file objective evidence.[9] Neither the board nor the examiner, however, gave such notice, and, therefore, appellants were led to believe, albeit erroneously, that they had satisfied their burden of going forward with objective evidence to rebut the prima facie case of obviousness. … In view of the PTO's failure to challenge the sufficiency of appellants' rebuttal evidence until this appeal, when appellants could no longer offer evidence, we conclude that it is necessary to vacate the board's decision… and to remand the case to afford appellants the opportunity to submit objective evidence of unexpected results.

[9] Where the board makes a decision advancing a position or rationale new to the proceedings, an applicant must be afforded an opportunity to respond to that position or rationale by submission of contradicting evidence. *In re Eynde*, 480 F.2d 1364, 178 USPQ 470 (CCPA 1973). Accordingly, if the board or the examiner in this case had stated that there was no objective evidence, appellants would have been entitled to respond by filing such evidence.

[46] *In re Eynde*, 480 F.2d 1364, 1371, 178 USPQ 470, 475 (CCPA 1973) (even though Board's new rationale, based on the Eynde patent, was in response to arguments made in the appeal Reply Brief, it was nonetheless a "new ground"), *reaffirmed by Kronig*, 539 F.2d at 1303, 190 USPQ at 427; *Ex parte Kozek*, Appeal No. 95-4678, 1995 WL 1747751 at *3-4, http://www.uspto.gov/go/dcom/bpai/ decisions/fd954678.pdf at 7-9 (BPAI Sept. 16, 1997) (expressly acknowledging that appellant's argument overcomes the examiner's stated reasons, but entering a "new ground of rejection" based on a different analysis of the identical references).

[47] *Ex parte Mathur*, Appeal No. 95-4103, 1996 WL 1795838 at *9, http://www.uspto.gov/go/dcom/bpai/decisions/fd954103.pdf at 20-21 (BPAI June 26, 1996) explains as follows:

> The examiner did not notify appellants that the arguments premised upon so-called unexpected properties were deficient since they were not supported by objective evidence. As set forth in *In re De Blauwe*, 736 F.2d 699, 705-06, 222 USPQ 191, 197 (Fed. Cir. 1984), if the examiner had previously pointed this out to appellants, "appellants would, at least, have had notice and would have had an opportunity to file objective evidence" (footnote omitted). The examiner's failure to put appellants on notice as to the lack of objective evidence in support of their argument concerning unexpected properties constitutes a second separate reason to denominate our affirmance of the examiner's decision as a new ground of rejection under 37 C.F.R. § 1.196(b).

See also quote from *In re DeBlauwe* in footnote 45

This flows from basic principles of examination: it is always the examiner's burden to take the first step of stating all elements of a *prima facie* case of unpatentability.[48] For example, 37 C.F.R. § 1.104(c)(2) states that it is the examiner's duty in the first instance to designate the portions relied on "as nearly as practicable," and "clearly explain" the correspondence of any complex reference to any claim being rejected, in any case except a pure § 102 rejection on a reference that is co-extensive with the claims.[49] The courts and the Board have noted that Applicants cannot, and therefore are not obligated to, reply to issues that the examiner has not raised. *See* 37 C.F.R. § 1.111(b) (reply must "point[ ] out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action" – no duty to go beyond the written action). Applicants are under no duty to anticipate issues that an examiner could have raised – even should have raised – but did not.[50] The rules provide only one procedural mechanism for an examiner when an applicant's arguments or evidence require a new position or rationale: non-final rejection.

---

[48] 35 U.S.C. § 102 (patent "shall" be granted, "unless" PTO establishes unpatentability); 37 C.F.R. §§ 1.104, 1.113 (actions must be "complete" and "clearly state" reasons); MPEP § 2142 (burden rests with examiner to "show" unpatentability); 5 U.S.C. §§ 551-559; *Wiechert*, 370 F.2d at 963-64, 152 USPQ at 251-52, *citing* 37 C.F.R. § 1.106, now § 1.104(c)(2); *see also In re Oetiker*, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (Plager, J., concurring) ("The examiner cannot sit mum, leaving the applicant to shoot arrows into the dark hoping to somehow hit a secret objection harbored by the examiner.").

[49] *See also Wiechert*, 370 F.2d at 963-64, 152 USPQ at 251-52 ("This point seems to be appreciated by the Patent Office itself as its Rule 106(b) [now 1.104(c)(2)] provides, *inter alia*, that: "When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable.").

[50] *Wiechert*, 370 F.2d at 933, 152 USPQ 251-52 (applicants "cannot practically" address all that "might be mentioned in a particular reference"); *Ex parte Lachut*, Appeal No. 2001-0933, 2002 WL 31257834 at *5, http://www.uspto.gov/go/dcom/bpai/decisions/ fd010933.pdf at 9 (BPAI Mar. 14, 2002) ("The entire [new analysis of existing references] is new and should have and could have been raised earlier," underline added); *see also Ex parte Mehta*, Appeal No. 1999-2683, 2002 WL 1801560 at *4, …/fd992683.pdf at 11 (BPAI Jul 30, 2001) (Board rejects examiner's attempt to untimely "twist the rejection around," even though based on the same references).

Attachment H

Office of Management and Budget

Circular A-4

Circular A-4

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

Subject: Regulatory Analysis

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (http://www.whitehouse.gov/omb/inforeg/riaguide.html), which was issued as a guidance in 2000 (http://www.whitehouse.gov/omb/memoranda/m00-08.pdf), and reaffirmed in 2001 (http://www.whitehouse.gov/omb/memoranda/m01-23.html). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions[1]

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects –

[1] We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

good and bad – of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis.[2] Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a "threshold" analysis to evaluate their significance. Threshold or "break-even" analysis answers the question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a "no action" baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a "next best" alternative are also especially useful.

[2] See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material

failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people ... ."

Executive Order 12866 also states that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.[3] From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. "Public goods," such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power

[3] See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services, for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively "available," they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;

- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

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.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and noncompliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in

some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a

program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in

estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure.[4] By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section "*Developing Benefit and Cost Estimates.*"

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

Cost-Effectiveness Analysis[5]

[4] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.
[5] For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.[6]

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society – whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes

[6] Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

called “total” costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of “effectiveness”, final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected “outcome” measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation’s different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of *some* but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative – that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures.

There are relatively simple measures such as the number of lives saved, cases of cancer reduced, and cases of paraplegia prevented. Sometimes these measures account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of "equivalent lives" (ELs) saved and the number of "quality-adjusted life years" (QALYs) saved.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g.,

asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g, the elderly and the poor) and thus have a strong interest in morbidity measurement[7], and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences.[8] For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay-measures.[9] Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for

---

[7] Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.

[8] Pliskin JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.

[9] Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

Distributional Effects

Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

General Issues

1. Scope of Analysis

Your analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately. The time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule.

2. Developing a Baseline

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting expected benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and
- the degree of compliance by regulated entities with other regulations.

It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming "no change" in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in the sensitivity analyses. For each baseline you use, you should identify the key uncertainties in your forecast.

EPA's 1998 final PCB disposal rule provides a good example of using different baselines. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile "shredder fluff" in municipal landfills -- reduced the cost of the program by more than $500 million per year.

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.

3. Evaluation of Alternatives

You should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. The previous discussion outlines examples of appropriate alternatives. Where there is a "continuum" of alternatives for a standard (such as the level of stringency), you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose reasonable alternatives deserving careful consideration. In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline. Whenever you report the benefits and costs of alternative options, you should present both total and incremental benefits and costs. You should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.[10] It is important to emphasize that incremental effects are simply differences between successively more stringent alternatives. Results involving a comparison to a "next best" alternative may be especially useful.

In some cases, you may decide to analyze a wide array of options. In 1998, DOE analyzed a large number of options in setting new energy efficiency standards for refrigerators and freezers and produced a rich amount of information on their relative effects. This analysis -- examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers -- enabled DOE to select an option that produced $200 more in estimated net benefits per refrigerator than the least attractive option.

[10] For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals. For each alternative that is more stringent than the least stringent alternative, you should estimate the incremental benefits and costs relative to the closest less-stringent alternative.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.

4. Transparency and Reproducibility of Results

Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information.

A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates.

To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings. You should also disclose the use of outside consultants, their qualifications, and history of contracts and employment with the agency (e.g., in a preface to the RIA). Where other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis, you should apply especially rigorous robustness checks to analytic results and document the analytical checks used.

Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" ("data quality guidelines") http://www.whitehouse.gov/omb/fedreg/reproducible.html.

Developing Benefit and Cost Estimates

1. Some General Considerations

The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars (for more on discounting see "*Discount Rates*" below);
- list the benefits and costs you can quantify, but cannot monetize, including their timing;
- describe benefits and costs you cannot quantify; and
- identify or cross-reference the data or studies on which you base the benefit and cost estimates.

When benefit and cost estimates are uncertain (for more on this see "*Treatment of Uncertainty*" below), you should report benefit and cost estimates (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and costs and include the upper and lower bound estimates as complements to central tendency and other estimates.

If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.

2. The Key Concepts Needed to Estimate Benefits and Costs

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost.

WTP and WTA are comparable measures under special circumstances. WTP and WTA measures may be comparable in the following situations: if a regulation affects a price change rather than a quantity change; the change being evaluated is small; there are reasonably close substitutes available; and the income effect is small.[11] However, empirical evidence from experimental economics and psychology shows that even when income/wealth effects are "small", the measured differences between WTP and WTA can be large.[12] WTP is generally

[11] See Hanemann WM (1991), *American Economic Review*, 81(3), 635-647.
[12] See Kahneman D, Knetsch JL, and Thaler RH (1991), "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias," *Journal of Economic Perspectives* 3(1), 192-206.

considered to be more readily measurable. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory analysis.

Market prices provide rich data for estimating benefits and costs based on willingness-to-pay if the goods and services affected by the regulation are traded in well-functioning competitive markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus[13]) of that product, taking into account the mitigating effects of potential substitutes.

The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities.

To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any cost savings as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative. However, you should not assume that the "avoided" costs of not doing another regulatory alternative represent the benefits of a regulatory action where there is no direct, necessary relationship between the two. You should also be careful when the costs avoided are attributable to an existing regulation. Even when there is a direct relationship between the two regulatory actions, the use of avoided costs is problematic because the existing regulation may not maximize net benefits and thus may itself be questionable policy. (See the section, "Direct Use of Market Data," for more detail.)

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, you need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on revealed preference methods can be quite useful. As one example, analysts sometimes use "hedonic price equations" based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest. The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For instance, a house is a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for

[13] Consumer surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producer surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

the implicit price of public goods that are not directly traded in markets. An analyst can develop implicit price estimates for public goods like air quality and access to public parks by assessing the effects of these goods on the housing market. Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

You need to guard against double-counting, since some attributes are embedded in other broader measures. To illustrate, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, an analysis that fails to incorporate the consequence of land use changes when accounting for costs will not capture the full effects of regulation.

3. Revealed Preference Methods

Revealed preference methods develop estimates of the value of goods and services -- or attributes of those goods and services -- based on actual market decisions by consumers, workers and other market participants. If the market participant is well informed and confronted with a real choice, it may be feasible to determine accurately and precisely the monetary value needed for a rulemaking. There is a large and well-developed literature on revealed preference in the peer-reviewed, applied economics literature.

Although these methods are well grounded in economic theory, they are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data. When designing or evaluating a revealed preference study, the following principles should be considered:

- the market should be competitive. If the market isn't competitive (e.g., monopoly, oligopoly), then you should consider making adjustments such that the price reflects the true value to society (often called the "shadow price");
- the market should not exhibit a significant information gap or asymmetric information problem. If the market suffers from information problems, then you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the market should not exhibit an externality. In this case, you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the specific market participants being studied should be representative of the target populations to be affected by the rulemaking under consideration;
- a valid research design and framework for analysis should be adopted. Examples include using data and/or model specifications that include the markets for substitute and complementary goods and services and using reasonably unrestricted functional forms. When specifying substitute and complementary goods, the analysis should preferably be

based on data about the range of alternatives perceived by market participants. If such data are not available, you should adopt plausible assumptions and describe the limitations of the analysis.

- the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique; and
- the results should be consistent with economic theory.

You should also determine whether there are multiple revealed-preference studies of the same good or service and whether anything can be learned by comparing the methods, data and findings from different studies. Professional judgment is required to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used in regulatory analysis despite their technical weaknesses (e.g., due to the absence of other evidence), the regulatory analysis should discuss any biases or uncertainties that are likely to arise due to those weaknesses. If a study has major weaknesses, the study should not be used in regulatory analysis.

a. Direct Uses of Market Data

Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services due to market imperfections or government intervention. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the shadow price. Suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the crop yield increase as a result of the controls. That value is typically measured by the price of the crop. However, if the price is held above the market price by a government program that affects supply, a value estimate based on this price may not reflect the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

Other goods whose market prices may not reflect their true value include those whose production or consumption results in substantial (1) positive or negative external effects or (2) transfer payments. For example, the observed market price of gasoline may not reflect marginal social value due to the inclusion of taxes, other government interventions, and negative externalities (e.g., pollution). This shadow price may also be needed for goods whose market price is substantially affected by existing regulations that do not maximize net benefits.

b. Indirect Uses of Market Data

Many goods or attributes of goods that are affected by regulation--such as preserving environmental or cultural amenities--are not traded directly in markets. The value for these

goods or attributes arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits and/or costs of regulatory action.

"Use values" arise where an individual derives satisfaction from using the resource, either now or in the future. Use values are associated with activities such as swimming, hunting, and hiking where the individual makes use of the natural environment.

"Non-use values" arise where an individual places value on a resource, good or service even though the individual will not use the resource, now or in the future. Non-use value includes bequest and existence values.

General altruism for the health and welfare of others is a closely related concept but may not be strictly considered a "non-use" value.[14] A general concern for the welfare of others should supplement benefits and costs equally; hence, it is not necessary to measure the size of general altruism in regulatory analysis. If there is evidence of selective altruism, it needs to be considered specifically in both benefits and costs.

Some goods and services are indirectly traded in markets, which means that their value is reflected in the prices of related goods and services that are directly traded in markets. Their use values are typically estimated through revealed preference methods. Examples include estimates of the values of environmental amenities derived from travel-cost studies, and hedonic price models that measure differences or changes in the value of real estate. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior. Also, you should take particular care in designing protocols for reliably estimating the values of these attributes.

4. Stated Preference Methods

Stated Preference Methods (SPM) have been developed and used in the peer-reviewed literature to estimate both "use" and "non-use" values of goods and services. They have also been widely used in regulatory analyses by Federal agencies, in part, because these methods can be creatively employed to address a wide variety of goods and services that are not easy to study through revealed preference methods.

The distinguishing feature of these methods is that hypothetical questions about use or non-use values are posed to survey respondents in order to obtain willingness-to-pay estimates relevant to benefit or cost estimation. Some examples of SPM include contingent valuation, conjoint analysis and risk-tradeoff analysis. The surveys used to obtain the health-utility values used in CEA are similar to stated-preference surveys but do not entail monetary measurement of value. Nevertheless, the principles governing quality stated-preference research, with some obvious exceptions involving monetization, are also relevant in designing quality health-utility research.

[14] See McConnell KE (1997), *Journal of Environmental Economics and Management*, *32*, 22-37.

When you are designing or evaluating a stated-preference study, the following principles should be considered:

- the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;
- willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;
- the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;
- the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;
- the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;
- response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;
- the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;
- documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);
- the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used.

The challenge in designing quality stated-preference studies is arguably greater for non-use values and unfamiliar use values than for familiar goods or services that are traded (directly or indirectly) in market transactions. The good being valued may have little meaning to respondents, and respondents may be forming their valuations for the first time in response to the questions posed. Since these values are effectively constructed by the respondent during the elicitation, the instrument and mode of administration should be rigorously pre-tested to make sure that responses are not simply an artifact of specific features of instrument design and/or mode of administration.

Since SPM generate data from respondents in a hypothetical setting, often on complex and unfamiliar goods, special care is demanded in the design and execution of surveys, analysis of the results, and characterization of the uncertainties. A stated-preference study may be the only way to obtain quantitative information about non-use values, though a number based on a poor quality study is not necessarily superior to no number at all. Non-use values that are not quantified should be presented as an "intangible" benefit or cost.

If both revealed-preference and stated-preference studies that are directly applicable to regulatory analysis are available, you should consider both kinds of evidence and compare the findings. If the results diverge significantly, you should compare the overall size and quality of the two bodies of evidence. Other things equal, you should prefer revealed preference data over stated preference data because revealed preference data are based on actual decisions, where market participants enjoy or suffer the consequences of their decisions. This is not generally the case for respondents in stated preference surveys, where respondents may not have sufficient incentives to offer thoughtful responses that are more consistent with their preferences or may be inclined to bias their responses for one reason or another.

5. Benefit-Transfer Methods

It is often preferable to collect original data on revealed preference or stated preference to support regulatory analysis. Yet conducting an original study may not be feasible due to the time and expense involved. One alternative to conducting an original study is the use of "benefit transfer" methods. (The transfer may involve cost determination as well). The practice of "benefit transfer" began with transferring existing estimates obtained from indirect market and stated preference studies to new contexts (i.e., the context posed by the rulemaking). The principles that guide transferring estimates from indirect market and stated preference studies should apply to direct market studies as well.

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification.

In conducting benefit transfer, the first step is to specify the value to be estimated for the rulemaking. You should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows you to "zero in" on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

- The selected studies should be based on adequate data, sound and defensible empirical methods and techniques.
- The selected studies should document parameter estimates of the valuation function.
- The study context and policy context should have similar populations (e.g., demographic characteristics). The market size (e.g., target population) between the study site and the policy site should be similar. For example, a study valuing water quality improvement in Rhode Island should not be used to value policy that will affect water quality throughout the United States.
- The good, and the magnitude of change in that good, should be similar in the study and policy contexts.
- The relevant characteristics of the study and the policy contexts should be similar. For example, the effects examined in the original study should be "reversible" or "irreversible" to a degree that is similar to the regulatory actions under consideration.
- The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of WTA measures while the rights in the rulemaking context support the use of WTP measures, benefit transfer is not appropriate.
- The availability of substitutes across study and policy contexts should be similar.

If you can choose between transferring a function or a point estimate, you should transfer the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer).[15]

Finally, you should not use benefit transfer in estimating benefits if:

- resources are unique or have unique attributes. For example, if a policy change affects snowmobile use in Yellowstone National Park, then a study valuing snowmobile use in the state of Michigan should not be used to value changes in snowmobile use in the Yellowstone National Park.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or benefit functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyon, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an *"ex ante"* valuation estimate to an *"ex post"* policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal

[15] See Loomis JB (1992), *Water Resources Research*, *28*(3), 701-705 and Kirchoff, S, Colby, BG, and LaFrance, JT (1997), *Journal of Environmental Economics and Management*, *33*, 75-93.

changes in a policy context involving large changes in the quantity of the good.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. Professional judgment is required in determining whether a particular transfer is too speculative to use in regulatory analysis.

6. Ancillary Benefits and Countervailing Risks

Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks).

You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks. However, highly speculative or minor consequences may not be worth further formal analysis. Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks. For instance, a recent study suggested that weight-based, fuel-economy standards could achieve energy savings with fewer safety risks and employment losses than would occur under the current regulatory structure.

Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks. If monetization is not feasible, quantification should be attempted through use of informative physical units. If both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side. Although it is theoretically appropriate to include disbenefits on the cost side, legal and programmatic considerations generally support subtracting the disbenefits from direct benefits.

7. Methods for Treating Non-Monetized Benefits and Costs

Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions. However, some important benefits and costs (e.g., privacy protection) may be inherently too difficult to quantify or monetize given current

data and methods. You should carry out a careful evaluation of non-quantified benefits and costs. Some authorities[16] refer to these non-monetized and non-quantified effects as "intangible".

a. Benefits and Costs that are Difficult to Monetize

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify but cannot monetize increases in water quality and fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis.

b. Benefits and Costs that are Difficult to Quantify

If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include information on the key reason(s) why they cannot be quantified. In one instance, you may know with certainty the magnitude of a risk to which a substantial, but unknown, number of individuals are exposed. In another instance, the existence of a risk may be based on highly speculative assumptions, and the magnitude of the risk may be unknown.

For cases in which the unquantified benefits or costs affect a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantified benefits and costs, and use your professional judgment to highlight (e.g., with categories or rank ordering) those that you believe are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

While the focus is often placed on difficult to quantify benefits of regulatory action, some costs are difficult to quantify as well. Certain permitting requirements (e.g., EPA's New Source Review program) restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motor bikes, may adversely affect the performance of the vehicles in terms of driveability and 0 to 60 miles per hour acceleration. Again, the cost associated with the loss of these attributes may be difficult to quantify and monetize. They need to be analyzed qualitatively.

[16] Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a WTP measure is the conceptually appropriate measure as compared to other alternatives (e.g., cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the WTP measure for health and safety allows you to directly compare your results to the other benefits and costs in your analysis, which will typically be based on WTP.

If well-conducted revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you should use valid and relevant data from stated-preference studies. You will need to use your professional judgment when you are faced with limited information on revealed preference studies and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods compared to revealed preference methods is that they can be tailored to address the ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed previously, you should be cautious about using values from stated-preference studies and describe in the analysis the drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences are also important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (e.g., birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state is necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) the private demand for prevention of the nonfatal health effect, to be represented by the

preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Fatality Risks

Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance. Agencies may choose to monetize these benefits. The willingness-to-pay approach is the best methodology to use if reductions in fatality risk are monetized.

Some describe the monetized value of small changes in fatality risk as the "value of statistical life" (VSL) or, less precisely, the "value of a life." The latter phrase can be misleading because it suggests erroneously that the monetization exercise tries to place a “value” on individual lives. You should make clear that these terms refer to the measurement of willingness to pay for reductions in only small risks of premature death. They have no application to an identifiable individual or to very large reductions in individual risks. They do not suggest that any individual's life can be expressed in monetary terms. Their sole purpose is to help describe better the likely benefits of a regulatory action.

Confusion about the term "statistical life" is also widespread. This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two "statistical lives" extended per year (2 million people x 1/1,000,000 = 2). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives extended.

The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. A considerable body of academic literature is available on this subject. This literature involves either explicit or implicit valuation of fatality risks, and generally involves the use of estimates of

VSL from studies on wage compensation for occupational hazards (which generally are in the range of 10^{-4} annually), on consumer product purchase and use decisions, or from an emerging literature using stated preference approaches. A substantial majority of the resulting estimates of VSL vary from roughly $1 million to $10 million per statistical life.[17]

There is a continuing debate within the economic and public policy analysis community on the merits of using a single VSL for all situations versus adjusting the VSL estimates to reflect the specific rule context. A variety of factors have been identified, including whether the mortality risk involves sudden death, the fear of cancer, and the extent to which the risk is voluntarily incurred.[18] The consensus of EPA's recent Science Advisory Board (SAB) review of this issue was that the available literature does not support adjustments of VSL for most of these factors. The panel did conclude that it was appropriate to adjust VSL to reflect changes in income and any time lag in the occurrence of adverse health effects.

The age of the affected population has also been identified as an important factor in the theoretical literature. However, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates.[19]

Another way that has been used to express reductions in fatality risks is to use the life expectancy method, the "value of statistical life-years (VSLY) extended." If a regulation protects individuals whose average remaining life expectancy is 40 years, a risk reduction of one fatality is expressed as "40 life-years extended." Those who favor this alternative approach emphasize that the value of a statistical life is not a single number relevant for all situations. In particular, when there are significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied in the labor market studies, they prefer to adopt a VSLY approach to reflect those differences. You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Longevity may be only one of a number of relevant considerations pertaining to the rule. You should keep in mind that regulations with greater numbers of life-years extended are not necessarily better than regulations with fewer numbers of life-years extended. In any event, when you present estimates based on the VSLY method, you should adopt a larger VSLY estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety.[20]

The valuation of fatality risk reduction is an evolving area in both results and methodology. Hence, you should utilize valuation methods that you consider appropriate for the

---

[17] See Viscusi WK and Aldy JE, *Journal of Risk and Uncertainty* (forthcoming) and Mrozek JR and Taylor LO (2002), *Journal of Policy Analysis and Management*, *21*(2), 253-270.

[18] Distinctions between "voluntary" and "involuntary" should be treated with care. Risks are best considered to fall within a continuum from "voluntary" to "involuntary" with very few risks at either end of this range. These terms are also related to differences in the cost of avoiding risks.

[19] Graham JD (2003), Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules. This memorandum can be found at http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf

[20] Office of Information and Regulatory Affairs, OMB, Memorandum to the President's Management Council, ibid.

regulatory circumstances. Since the literature-based VSL estimates may not be entirely appropriate for the risk being evaluated (e.g., the use of occupational risk premia to value reductions in risks from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risk being evaluated. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate the methodology used and document your choice of a particular methodology. You should explain any significant deviations from the prevailing state of knowledge. If you use different methodologies in different rules, you should clearly disclose the fact and explain your choices.

c. Valuation of Reductions in Health and Safety Risks to Children

The valuation of health outcomes for children and infants poses special challenges. It is rarely feasible to measure a child's willingness to pay for health improvement and an adult's concern for his or her own health is not necessarily relevant to valuation of child health. For example, the wage premiums demanded by workers to accept hazardous jobs are not readily transferred to rules that accomplish health gains for children.

There are a few studies that examine parental willingness to pay to invest in health and safety for their children. Some of these studies suggest that parents may value children's health more strongly than their own health. Although this parental perspective is a promising research strategy, it may need to be expanded to include a societal interest in child health and safety.

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise.[21]

Discount Rates

Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when the actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule.

[21] For more information, see Dockins C., Jenkins RR, Owens N, Simon NB, and Wiggins LB (2002), *Risk Analysis*, 22(2), 335-346.

In presenting the stream of benefits and costs, it is important to measure them in constant dollars to avoid the misleading effects of inflation in your estimates. If the benefits and costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

1. The Rationale for Discounting

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. (This is a separate calculation from the adjustment needed to remove the effects of future inflation.) Benefits or costs that occur sooner are generally more valuable. The main rationales for the discounting of future impacts are:

(a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.
(b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.
(c) Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

There is wide agreement with point (a). Capital investment is productive, but that point is not sufficient by itself to explain positive interest rates and observed saving behavior. To understand these phenomena, points (b) and (c) are also necessary. If people are really indifferent between consumption now and later, then they should be willing to forgo current consumption in order to consume an equal or slightly greater amount in the future. That would cause saving rates and investment to rise until interest rates were driven to zero and capital was no longer productive. As long as we observe positive interest rates and saving rates below 100 percent, people must be placing a higher value on current consumption than on future consumption.

To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate. The formula is $1/ (1+ \text{the discount rate})^t$ where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in this way are called "discounted present values" or simply "present values". When, and only when, the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

2. Real Discount Rates of 3 Percent and 7 Percent

OMB's basic guidance on the discount rate is provided in OMB Circular A-94 (http://www.whitehouse.gov/omb/circulars/index.html). This Circular points out that the analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption and to discount them at the rate consumers and savers would normally use in discounting future consumption benefits. This is sometimes called the "shadow price" approach to discounting because doing such calculations requires you to value benefits and costs using shadow prices, especially for capital goods, to correct for market distortions. These shadow prices are not well established for the United States. Furthermore, the distribution of impacts from regulations on capital and consumption are not always well known. Consequently, any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

As a default position, OMB Circular A-94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A-94 in 1992 after extensive internal review and public comment. In a recent analysis, OMB found that the average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A-94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

Economic distortions, including taxes on capital, create a divergence between the rate of return that savers earn and the private rate of return to capital. This divergence persists despite the tendency for capital to flow to where it can earn the highest rate of return. Although market forces will push after-tax rates of return in different sectors of the economy toward equality, that process will not equate pre-tax rates of return when there are differences in the tax treatment of investment. Corporate capital, in particular, pays an additional layer of taxation, the corporate income tax, which requires it to earn a higher pre-tax rate of return in order to provide investors with similar after-tax rates of return compared with non-corporate investments. The pre-tax rates of return better measure society's gains from investment. Since the rates of return on capital are higher in some sectors of the economy than others, the government needs to be sensitive to possible impacts of regulatory policy on capital allocation.

The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real terms on a pre-tax basis. For example, the yield on 10-year Treasury notes has averaged 8.1 percent since

1973 while the average annual rate of change in the CPI over this period has been 5.0 percent, implying a real 10-year rate of 3.1 percent.

For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present-value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. You should present a similar analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may lie outside the range of 3 to 7 percent. For example, the average real rate of return on corporate capital in the United States was approximately 10 percent in the 1990s, returning to the same level observed in the 1950s and 1960s. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a further sensitivity analysis as well as using the 3 and 7 percent rates.

3. Time Preference for Health-Related Benefits and Costs

When future benefits or costs are health-related, some have questioned whether discounting is appropriate, since the rationale for discounting money may not appear to apply to health. It is true that lives saved today cannot be invested in a bank to save more lives in the future. But the resources that would have been used to save those lives can be invested to earn a higher payoff in future lives saved. People have been observed to prefer health gains that occur immediately to identical health gains that occur in the future. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate. This consensus applies to both BCA and CEA.

A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short. For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population.

When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period. As a general matter, cessation lags will only apply to populations with at least some high-level exposure (e.g., before the rule

takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, accounting for total cumulative exposure and age at the time of exposure reduction. The present-value benefits estimate could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits stemming from reduction in public exposure to radon in drinking water have adopted this approach. They were supported by formal risk-assessment models that allowed estimates of the timing of lung cancer incidence and mortality to vary in response to different radon exposure levels.[22]

In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgment as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe that the two are different. When the average lag time between exposures and disease is unknown, a range of plausible alternative values for the time lag should be used in your analysis.

4. Intergenerational Discounting

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate time preference in their own consumption behavior, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act with some consideration of their interest.

One way to do this would be to follow the same discounting techniques described above and supplement the analysis with an explicit discussion of the intergenerational concerns (how future generations will be affected by the regulatory decision). Policymakers would be provided with this additional information without changing the general approach to discounting.

Using the same discount rate across generations has the advantage of preventing time-inconsistency problems. For example, if one uses a lower discount rate for future generations, then the evaluation of a rule that has short-term costs and long-term benefits would become more favorable merely by waiting a year to do the analysis. Further, using the same discount rate across generations is attractive from an ethical standpoint. If one expects future generations to be better off, then giving them the advantage of a lower discount rate would in effect transfer resources from poorer people today to richer people tomorrow.

Some believe, however, that it is ethically impermissible to discount the utility of future generations. That is, government should treat all generations equally. Even under this approach,

[22] Committee on Risk Assessment of Exposure to Radon in Drinking Water, Board on Radiation Effects Research, Commission on Life Sciences (1996), *Risk Assessment of Radon in Drinking Water*, National Research Council, National Academy Press, Washington, DC.

it would still be correct to discount future costs and consumption benefits generally (perhaps at a lower rate than for intragenerational analysis), due to the expectation that future generations will be wealthier and thus will value a marginal dollar of benefits or costs by less than those alive today. Therefore, it is appropriate to discount future benefits and costs relative to current benefits and costs, even if the welfare of future generations is not being discounted. Estimates of the appropriate discount rate appropriate in this case, from the 1990s, ranged from 1 to 3 percent per annum.[23]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. As explained by Martin Weitzman[24], in the limit for the deep future, the properly averaged certainty-equivalent discount factor (i.e., $1/[1+r]^t$) corresponds to the minimum discount rate having any substantial positive probability. From today's perspective, the only relevant limiting scenario is the one with the lowest discount rate – all of the other states at the far-distant time are relatively much less important because their expected present value is so severely reduced by the power of compounding at a higher rate.

If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent.

5. Time Preference for Non-Monetized Benefits and Costs

Differences in timing should be considered even for benefits and costs that are not expressed in monetary units, including health benefits. The timing differences can be handled through discounting. EPA estimated cost-effectiveness in its 1998 rule, "Control of Emissions from Nonroad Diesel Engines," by discounting both the monetary costs and the non-monetized emission reduction benefits over the expected useful life of the engines at the 7 percent real rate recommended in OMB Circular A-94.

Alternatively, it may be possible in some cases to avoid discounting non-monetized benefits. If the expected flow of benefits begins as soon as the cost is incurred and is expected to be constant over time, then annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. Such an analysis might produce an estimate of the annualized cost per ton of reduced emissions of a pollutant.

6. The Internal Rate of Return

The internal rate of return is the discount rate that sets the net present value of the discounted benefits and costs equal to zero. The internal rate of return does not generally

[23] Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.
[24] Weitzman ML In Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

provide an acceptable decision criterion, and regulations with the highest internal rate of return are not necessarily the most beneficial. Nevertheless, it does provide useful information and for many it will offer a meaningful indication of regulation's impact. You should consider including the internal rate of return implied by your regulatory analysis along with other information about discounted net present values.

Other Key Considerations

1. Other Benefit and Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values when they are significant:

- Private-sector compliance costs and savings;
- Government administrative costs and savings;
- Gains or losses in consumers' or producers' surpluses;
- Discomfort or inconvenience costs and benefits; and
- Gains or losses of time in work, leisure and/or commuting/travel settings.

Estimates of benefits and costs should be based on credible changes in technology over time. For example, retrospective studies may provide evidence that "learning" will likely reduce the cost of regulation in future years. The weight you give to a study of past rates of cost savings resulting from innovation (including "learning curve" effects) should depend on both its timeliness and direct relevance to the processes affected by the regulatory alternative under consideration. In addition, you should take into account cost-saving innovations that result from a shift to regulatory performance standards and incentive-based policies. On the other hand, significant costs may result from a slowing in the rate of innovation or of adoption of new technology due to delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones. In some cases agencies are limited under statute to consider only technologies that have been demonstrated to be feasible. In these situations, it may be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

When characterizing technology changes over time, you should assess the likely technology changes that would have occurred in the absence of the regulatory action (technology baseline). Technologies change over time in both reasonably functioning markets and imperfect markets. If you assume that technology will remain unchanged in the absence of regulation when technology changes are likely, then your analysis will over-state both the benefits and costs attributable to the regulation.

Occasionally, cost savings or other forms of benefits accrue to parties affected by a rule who also bear its costs. For example, a requirement that engine manufacturers reduce emissions from engines may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the engine purchasers, who also bear the costs of the technologies. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost

of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, you should examine and discuss why market forces would not accomplish these gains in the absence of regulation. As a general matter, any direct costs that are averted as a result of a regulatory action should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Benefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers. However, transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits, as long as the analysis is conducted from the United States perspective.

You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects. Examples of transfer payments include the following:

- Scarcity rents and monopoly profits
- Insurance payments
- Indirect taxes and subsidies

Treatment of Uncertainty

The precise consequences (benefits and costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be developed. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. You should begin your analysis of uncertainty at the earliest possible stage in developing your analysis. You should consider both the statistical variability of key elements underlying the estimates of benefits and costs (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge about the relevant relationships (for example, the uncertain knowledge of how some economic activities might affect future climate change).[25] By assessing the sources of uncertainty and the way in which benefit and cost estimates may be affected under plausible assumptions, you can shape your analysis to inform decision makers and the public about the effects and the uncertainties of alternative regulatory actions.

[25] In some contexts, the word "variability" is used as a synonym for statistical variation that can be described by a theoretically valid distribution function, whereas "uncertainty" refers to a more fundamental lack of knowledge. Throughout this discussion, we use the term "uncertainty" to refer to both concepts.

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced.[26] Any data and models that you use to analyze uncertainty should be fully identified. You should also discuss the quality of the available data used. Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified. In your presentation, you should delineate the strengths of your analysis along with any uncertainties about its conclusions. Your presentation should also explain how your analytical choices have affected your results.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For instance, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur.

When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information.

For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.[27] Delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

"Real options" methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay—including any harm to public health, safety, and the environment—need to be analyzed carefully.

1. Quantitative Analysis of Uncertainty

[26] When disseminating information, agencies should follow their own information quality guidelines, issued in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002).
[27] Clemen RT (1996), *Making Hard Decisions: An Introduction to Decision Analysis*, second edition, Duxbury Press, Pacific Grove.

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as benefit-cost analysis. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. Attention should be devoted to first resolving or studying the uncertainties that have the largest potential effect on decision making. Many times these will be the largest sources of uncertainties. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions.

For major rules involving annual economic effects of $1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs. In summarizing the probability distributions, you should provide some estimates of the central tendency (e.g., mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes, and they do not permit calculation of an expected value of net benefits. In many health and safety rules, economists conducting benefit-cost analyses must rely on formal risk assessments that address a variety of risk management questions such as the baseline risk for the affected population, the safe level of exposure or, the amount of risk to be reduced by various interventions. Because the answers to some of these questions are directly used in benefits analyses, the risk assessment methodology must allow for the determination of expected benefits in order to be comparable to expected costs. This means that conservative assumptions and defaults (whether motivated by science policy or by precautionary instincts), will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value. Whenever it is possible to characterize quantitatively the probability distributions, some estimates of expected value (e.g., mean and

median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes. For rules that exceed the $1 billion annual threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to $1 billion, you should seek to use more rigorous approaches with higher consequence rules. This is especially the case where net benefits are close to zero. More rigorous uncertainty analysis may not be necessary for rules in this category if simpler techniques are sufficient to show robustness. You may consider the following analytical approaches that entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion annual threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find "switch points" -- critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion annual threshold require a formal treatment.
- Apply a formal probabilistic analysis of the relevant uncertainties – possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods.[28] Such a formal analytical approach is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty.[29] In general, experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs. You should

[28] The purpose of Delphi methods is to generate suitable information for decision making by eliciting expect judgment. The elicitation is conducted through a survey process which eliminates the interactions between experts. See Morgan MG and Henrion M (1990), *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Riskand Policy Analysis*, Cambridge University Press.

[29] Cooke RM (1991), *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press.

pay attention to correlated inputs. Often times, the standard defaults in Monte Carlo and other similar simulation packages assume independence across distributions. Failing to correctly account for correlated distributions of inputs can cause the resultant output uncertainty intervals to be too large, although in many cases the overall effect is ambiguous. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Economic Values of Uncertain Outcomes

In developing benefit and cost estimates, you may find that there are probability distributions of values as well for each of the outcomes. Where this is the case, you will need to combine these probability distributions to provide estimated benefits and costs.

Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the "best estimates" of both benefits and costs with those of competing alternatives. These "best estimates" are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is "risk neutral" with respect to the regulatory alternatives. While this may not always be the case, you should in general assume "risk neutrality" in your analysis. If you adopt a different assumption on risk preference, you should explain your reasons for doing so.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

F. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a number of analytic requirements imposed by law and Executive Order. In addition to the regulatory analysis requirements of Executive Order 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." You should consider posting your RFA on the internet so the public can review your findings.

Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. Executive Order 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office. Under SBREFA, EPA and OSHA are required to consult with small business prior to developing a proposed rule that would have a significant effect on small businesses. OMB encourages other agencies to do so as well.

Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about benefits and costs prior to issuing a proposed or final rule (for which your agency published a proposed rule) that may result in aggregate expenditure by State, local, and tribal governments, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

Information Collection, Paperwork, and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy

Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance. This circular defines OMB's minimum quality standards for regulatory analysis.

Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321-4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major Federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 C.F.R. 1500-1508) and associated guidance for implementation of NEPA, available through CEQ's website (http://www.whitehouse/gov/ceq/).

Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further guidance, see OMB Memorandum 01-27 ("Guidance on Implementing Executive Order 13211", July 13, 2001), available on OMB's website.

G. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories: monetized quantified, but not monetized; and qualitative, but not quantified or monetized.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of benefits and costs, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

You should develop quantitative estimates and convert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Qualitative Benefits and Costs

You should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). You should distinguish the effects that are likely to be significant enough to warrant serious consideration by decision makers from those that are likely to be minor.

Treatment of Benefits and Costs over Time

You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year in which the final rule will begin to have effects, even if the rule does not take effect immediately. Please report all monetized effects in 2001 dollars. You should convert dollars expressed in different years to 2001 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide expected-value estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required, but should be available upon request.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In a previous section, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use different estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of +/-$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of +/-$0.5 million.

Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflect transfers rather than net welfare gains to society, you should identify them as transfers rather than benefits or costs. You should also distinguish transfers caused by Federal budget actions -- such as those stemming from a rule affecting Social Security payments -- from those that involve transfers between non-governmental parties -- such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant efficiency effects in addition to distributional effects, you should report them.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, costs, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth.[30] Note that rules with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.

[30] The Regulatory Flexibility Act (5 U.S.C. 603(c), 604).

OMB #: **Agency/Program Office:**
Rule Title:
RIN#: **Date:**

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
monetized benefits				
Annualized quantified, but unmonetized, benefits				
unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
from whom to whom?				
Annualized monetized transfers: "off-budget"				
From whom to whom?				
Category	*Effects*			*Source Citation (RIA, preamble, etc.)*
Effects on State, local, and/or tribal governments				
Effects on small businesses				
Effects on wages				
Effects on growth				

H. Effective Date

The effective date of this Circular is January 1, 2004 for regulatory analyses received by OMB in support of proposed rules, and January 1, 2005 for regulatory analyses received by OMB in support of final rules. In other words, this Circular applies to the regulatory analyses for draft proposed rules that are formally submitted to OIRA after December 31, 2003, and for draft final rules that are formally submitted to OIRA after December 31, 2004. (However, if the draft proposed rule is subject to the Circular, then the draft final rule will also be subject to the Circular, even if it is submitted prior to January 1, 2005.) To the extent practicable, agencies should comply earlier than these effective dates. Agencies may, on a case-by-case basis, seek a waiver from OMB if these effective dates are impractical.

Attachment I

Request for Extension of Time

The Honorable Jon W. Dudas
Under Secretary of Commerce for Intellectual Property
Director, U.S. Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22313

Judges Fred McKelvey and Allen R. MacDonald
Board of Patent Appeals and Interferences
U.S. Patent and Trademark Office

Robert Clarke, as Paperwork Reduction Act administrator
Office of Patent Legal Administration
U.S. Patent and Trademark Office

RE: RIN 0651–AC12 (Rules of Practice Before the Board of Patent Appeals and Interferences in Ex Parte Appeals"), 71 FR 41472 (July 30, 2007) (Appeals Rule)

RIN 0651–AC00 ("Examination of Patent Applications That Include Claims Containing Alternative Language"), 71 FR 44992 (August 10, 2007) (Markush Practice Rule)

Dear Mr. Dudas,

I am writing to formally request that you significantly extend the public comment period for these recently published Notices of Proposed Rulemaking. Although the U.S. Patent and Trademark Office (USPTO) designated each as "not significant" under Executive Order 12866, both proposed rules appear to be very significant, and plausibly economically significant, under Section 2(f)(2) of the Executive Order.

The Appeals Rule would dramatically restructure the procedures used by the Board of Patent Appeals and Interferences (BPAI). These new procedures would significantly increase the cost of appealing first Office action rejections and reduce the likelihood that appellants can obtain a full and fair adjudication of patentability. USPTO provided a 60-day public comment period, which expires on September 28.

The Markush Practice Rule would radically change 50 years of practice in this important area. Many pharmaceutical and biotechnology patents would be difficult or impossible to prosecute under the proposed rules. USPTO provided a 60-day public comment period, which expires on October 9.

Recent Patent Office regulations have generated considerable controversy. The public comment process for these rules has been handicapped, as it has been in other recent cases, by the dearth of supporting documentation and policy analysis in USPTO's docket. Some of the analysis the Patent Office does report is problematic. For example, the Patent Office asserts that only 0.9% of small business patent applicants would be affected by the Appeals Rule. That ratio is obtained by taking the 4,000 appeals filed by small businesses in FY 2006 and dividing it by the 443,000 patent applications submitted that year. But these 4,000 appeals were 22% of the total number of appeals filed in FY 2006. Clearly, 22% is much different from 0.9% (71 Fed. Reg. 41484). If an appeals-to-applications ratio is meaningful at all, FY 2006 appeals should be compared to circa FY 2002 applications, not FY 2006 applications. Finding all the methodological flaws of this sort to assist the Office in preparing sound Paperwork Reduction and Regulatory Flexibility analyses will require significant work.

For these reasons, we respectfully request that you significantly extend the public comment period. That would not harm the Patent Office in any way, while better assuring that the public has a full opportunity to comment on these rules' vast implications for the U.S. patent system.

Sincerely,

/s/ David E. Boundy

Vice President, Assistant General Counsel Intellectual Property
Cantor Fitzgerald L.P.
110 East 59th St
New York, NY 10022
(212) 294-7848
(917) 677-8511 (FAX)