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Sent: Tuesday, February 15, 2011 11:58 AM
To: KSR_Guidance; Fonda, Kathleen; Laufer, Pinchus
Subject: Comments on KSR Guidelines update

Attached are my comments on the September KSR Guidelines Update. Thanks.

<<Comments on KSR Update 110215 1200 FINAL.pdf>>

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February 15, 2011

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Cc: The Honorable Gary Locke
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Attn: DOC oversight of PTO, and
reduction of PTO backlog, at § I at
page 3, and § II at page 12

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Attn: PTO “opt out” from Executive
Orders and OMB directives at § I
at pages 3-9

Re: Examination Guidelines Update: Developments in the Obviousness Inquiry After
KSR v. Teleflex (Docket No.: PTO–P–2010–0055), 75 Fed. Reg. 53643 (Sep. 1,
2010)¹

Dear Ms. Fonda and Mr. Laufer:

I write to comment on several administrative law aspects of the September 1, 2010 *KSR Guidelines Update* for examination of patent applications, and to offer some additional suggestions on how efficiency might be improved for both the Office and for applicants.

In the *KSR Guidelines Update*, the PTO continues its recent pattern of selective compliance with various provisions of administrative law. In recent weeks, the PTO officially refused to comply with directives that apply to all other agencies—specifically, Executive Order 12,866 and the Office of Management and Budget’s *Final Bulletin on Agency Good Guidance Practices*. The *KSR Guidelines Update* also breaches the Paperwork Reduction Act (PRA), the Administrative Procedure Act (APA), and § 2 of

¹ <http://www.gpo.gov:80/fdsys/pkg/FR-2010-09-01/pdf/2010-21646.pdf>

the Patent Act. In this letter, I ask that PTO reconsider its opinion that it has no duty to supervise examiners' compliance with the internal directives contained in Chapter 2100 of the MPEP. Chapter 2100 provides examiners clear, detailed written guidance for the examination of applications, guidance that would improve agency predictability and efficiency and reduce backlog, if only examiners followed it consistently. When examiners do not adhere to Chapter 2100, and applicants ask supervisors to hold them accountable, supervisors refuse to do so. This leaves every individual examiner free to make up rules and procedures *ad hoc*, ultimately creating more re-work for both applicants and for the Office. The PTO cannot reduce its backlog if examiners are left unsupervised and without internal accountability to ensure that regulations and guidance are followed. Random examination is inefficient examination.

I also draw the PTO's attention to several other issues relating to examination for obviousness that are not directly implicated in the *KSR Guidelines Update*, but that are ripe for review and correction.

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I. Continued noncompliance with Executive Order 12,866 and OMB’s directive on *Good Guidance Practices*

Many patent attorneys share my opinion, that the single biggest factor in the PTO’s backlog is the unpredictability of Office procedure. Where a PTO guidance document provides that if an applicant does x then the PTO will do y, it should be the case that an applicant can be assured that this will happen. Unfortunately, this is not the case. Oftentimes, y is not the PTO’s response to x—the examiner (or Petitions Office)

either ignores the regulation or guidance or provides an *ad hoc* exception that exists in no written document. The PTO does not have a culture of predictability and respect for written procedures, and consequently applicants cannot advance applications predictably

This single biggest factor in the backlog has a ready cure, the *Final Bulletin for Agency Good Guidance Practices*, a directive issued to all agencies in January 2007 by the Office of Management and Budget.² The *GGP Directive* is an internal government regulation, as confirmed by its plain language. Yet the PTO apparently has never assigned compliance responsibility to anyone. Because of PTO failure to implement this OMB directive, “rework” applications continue to increase and progress reducing the backlog is unnecessarily attenuated.

There are several requirements of the *GGP Directive* that are directly applicable to the *KSR Guidelines Update*, and several other provisions that would improve efficiency of all patent operations if they were implemented.

A. The *KSR Guidelines Update* is an “economically significant guidance document”

The *KSR Guidelines Update* is unquestionably a “guidance document[] disseminated to regulated entities or the general public that may reasonably be anticipated to ... (i) Lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, [or] competition:”³

- *KSR* is one the most important changes in patent law in a generation. Its potential economic effects vastly exceed the \$100 million threshold for economic significance.
- The *KSR Guidelines Update* affects the paperwork burden acknowledged by the PTO in its ICRs (roughly \$4 billion per year) in thus far uncounted ways. My informed guess is that at least 20% of that \$4 billion is directly attributable to obviousness issues. For example, the PTO acknowledges burden of over \$250 million per year for *appeals alone*, of which half or more is due to obviousness. It can hardly be questioned that the *KSR Guidelines Update* “may reasonably be anticipated to ... (i) Lead to an annual effect on the economy of \$100 million or more.”

² Office of Management and Budget, *Final Bulletin for Agency Good Guidance Practices*, OMB Memorandum M-07-07, http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/m07-07.pdf (Jan. 18, 2007), 72 Fed. Reg. 3432 (Jan. 25, 2007) (hereafter “*GGP Directive*”).

³ *GGP Directive* at 3439, § I(5).

- Two specific paragraphs of the *KSR Guidelines Update* create unnecessary procedural ambiguity that generates over \$100 million of annual paperwork burden.⁴ The effects of this ambiguity will be magnified several fold in compromised patent value.
- The *KSR Guidelines Update* is likely to have its greatest effects in the highest-innovation sectors of the economy. If PTO procedural issues governed by guidance have any multiplier effect, it is these sectors where effects will be most pronounced.

Thus, the *KSR Guidelines Update* is subject to the heightened procedural requirements for “economically significant guidance documents” of the *GGP Directive*. These procedures require, *inter alia*, that the PTO “[p]repare and post on the agency’s website a response-to-comments document.”⁵

The text of the *KSR Guidelines Update* indicates PTO has not followed these procedures so far and has no plan to do so. I spoke with Jennifer McDowell in the PTO’s Office of General Counsel to find out why the PTO had not observed these heightened procedures for the *KSR Guidelines Update*. Ms. McDowell said “the Office does not believe” that the *KSR Guidelines Update* is reasonably likely to have \$100 million in economic effect, because the *KSR Guidelines Update* is only a consolidation or interpretation (I don’t recall her exact words) of Federal Circuit Law. On this point, the Office’s “belief” is not a permissible basis to exclude the *KSR Guidelines Update* from coverage—the *GGP Directive* clearly says that economically significant effects are covered in such situations:

Guidance can have coercive effects or lead parties to alter their conduct. For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. ... While not legally binding, such a statement could reasonably be anticipated to lead to changes in behavior by the private sector ... such that it would lead to a significant economic effect. Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures of § IV.⁶

The mere fact that the *KSR Guidelines Update* provides far less certainty, and channels examiner discretion far less than it could, is likely to result in over \$100 million in additional paperwork burden from uncertainty alone. The economic effects flowing from both the Guidelines and this paperwork burden are currently unknown, and to date the PTO has shown no interest in credibly estimating them.

⁴ This is discussed in §§ II.A and II.B starting at page 12 below.

⁵ See the *GGP Directive* at § IV(1)(d).

⁶ See the preamble to the *GGP Directive* at pp. 9-10.

B. The PTO must prepare a “robust response to comments”

For economically significant guidance documents, the PTO must prepare a “robust response to comments.”⁷

IV. Notice and Public Comment for Economically Significant Guidance Documents.

1. In General: Except as provided in Section IV(2),⁸ when an agency prepares a draft of an economically significant guidance document, the agency shall:

- a. Publish a notice in the Federal Register announcing that the draft document is available;
- b. Post the draft document on the Internet and make it publicly available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts)
- c. Invite public comment on the draft document; and
- d. Prepare and post on the agency’s website a response-to-comments document.

I look forward to reviewing the PTO’s response to comments document that responds to the comments received.

C. The PTO’s failure to indicate the status of its guidance documents violates both the *GGP Directive* and the Paperwork Reduction Act

1. How the *KSR Guidelines Update* violates the *GGP Directive*

The *GGP Directive* requires the PTO to give notice to the public concerning which guidance documents are in effect and which are not:

III. Public Access and Feedback for Significant Guidance Documents.

1. Internet Access:

a. Each agency shall maintain on its website—or as a link on an agency’s website to the electronic list posted on a component or subagency’s website—a current list of its significant guidance documents in effect. The list shall include the name of each significant guidance document, any document identification number, and issuance and revision dates. The agency shall provide a link from the current list to each significant guidance document that is in effect. New significant guidance documents and their website links shall be added promptly to this list, no later than 30 days from the date of issuance.

b. The list shall identify significant guidance documents that have been added, revised or withdrawn in the past year.⁹

⁷ *GGP Directive* at page 17 (“The agency also must prepare a robust response-to-comments document and make it publicly available” (emphasis added)).

⁸ *GGP Directive* § IV(2) allows agency heads to issue exemptions after consultation with OMB in cases where compliance is not “feasible or appropriate.” No such exemption exists, and the factual predicates required for an exemption also are absent.

After diligent search, it appears that the PTO maintains no such web page. The closest approximation appears to be a list of “Memoranda to the Examining Corps,”¹⁰ but this page does not meet the requirements of the *GGP Directive*. It is incomplete; it does not include the required dates, and it does not distinguish guidance that is still in effect from guidance that is obsolete or withdrawn. For example, the following known guidance documents are not listed:

- The January 26, 2010 memorandum from Director Kappos regarding “non-transitory memory” claims¹¹
- The new revisions of the MPEP published in September 2007, July 2008, and July 2010
- Examiner Training Materials, Best Practices in Compact Prosecution¹²
- The numerous sets of examiner training materials issued in spring 2008 for use Office-wide and issued by a number of Technology Centers
- Written Description Guidelines Training Materials (March 2008)¹³
- The July 2005 memo creating “Pre-Appeal” review

More to the point, even the *KSR Guidelines Update* is not listed. It is inconceivable that the PTO would omit it from this list if the Office had intended for the list to comply with the *GGP Directive*.

Guidance documents that are obsolete are still listed as if they remain in effect, leaving the public confused as to which documents *are* in effect. For example, the PTO’s “Memoranda” page still lists the “Changes to Restriction form paragraphs” memo of April 2007 and “Changes to Restriction Form Paragraphs” of January 21, 2010, even though both of these memoranda were obsoleted after they were not incorporated into subsequent revisions of the MPEP.

The PTO’s noncompliance with even this elementary procedural aspect of the *GGP Directive* creates numerous uncertainties. For example, how much of MPEP § 2144 (concerning permissible evidentiary rationales) remains in effect in light of the *KSR Guidelines Update*? What is the interrelationship between the June 2010 *Bilski* guidelines and the January 2010 Kappos memorandum? Is the Kappos memorandum still in effect? The patent community does not know, because the PTO does not provide this essential information, and the information the PTO *does* provide is contradictory.

⁹ *GGP Directive* at § III((1)(1).

¹⁰ <http://www.uspto.gov/patents/law/exam/memoranda.jsp>

¹¹ http://www.uspto.gov/patents/law/notices/101_crm_20100127.pdf

¹² http://www.uspto.gov/patents/law/exam/compact_prosecution.pdf (2009)

¹³ <http://www.uspto.gov/web/menu/written.pdf>

The public can only guess at the priority and relationship between new examiner guidance and the MPEP.

D. Other unimplemented provisions of the *GGP Directive*

The *GGP Directive* has other applicable requirements that the PTO also has not implemented.

1. Written procedures for the approval of significant guidance documents.

The practice of issuing guidance must be organized systematically under the direct control of senior agency officials, as authorized in writing by the agency head:

II. Basic Agency Standards for Significant Guidance Documents.

1. Approval Procedures:

a. Each agency shall develop or have written procedures for the approval of significant guidance documents. Those procedures shall ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials.

The PTO's web site contains a wealth of information, but it does not have a document setting forth written procedures for the approval of significant guidance documents. I have made several inquiries to obtain these "written procedures," and apparently they do not exist.

2. Significant guidance documents must adhere to basic principles of administrative law.

It is a basic principle of administrative law that an agency cannot create regulatory requirements through guidance.¹⁴ This principle is explicitly reiterated in the *GGP Directive*:

2. Standard Elements: Each significant guidance document shall:

h. Not include mandatory language such as "shall," "must," "required" or "requirement," unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.

The MPEP includes many (perhaps thousands) of regulatory requirements. PTO personnel regularly require applicants to comply with provisions in the MPEP that are expressly advisory or suggestive, thereby "foreclose[ing] agency consideration of positions advanced by affected private parties."

¹⁴ 5 U.S.C. § 552(a), 44 U.S.C. § 3512.

3. The PTO has not designated an office to receive and address complaints regarding the Office's use of guidance.

The *GGP Directive* requires the PTO to appoint what could be called a "Good Guidance Officer," an official of sufficient rank and capability to implement the *GGP Directive* and ensure that the Office complies:

III. Public Access and Feedback for Significant Guidance Documents.

2. Public Feedback:

b. Each agency shall designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in this Bulletin or is improperly treating a significant guidance document as a binding requirement. The agency shall provide, on its website, the name and contact information for the office(s).

No such information is on the PTO's web site. Numerous inquires by myself and others have failed to elicit a credible reply. The PTO has not designated any office to implement the *GGP Directive*, nor has the Director assigned this responsibility to any person. A sure way to avoid receiving complaints is to never set up any procedure for accepting them. A sure way to avoid internal pressure to comply is never to assign anyone the authority and responsibility of ensuring compliance. To date, both practices are PTO policy with respect to the *GGP Directive*.

4. Employees require training in the proper interpretation and application of guidance.

For guidance to be an effective alternative to regulation, an agency's employees must understand the difference between rules and guidance. Further, they need to know when to consult senior agency officials rather than act on their own understanding. To this end the preamble to the *GGP Directive* asks agencies to train their employees:

Agencies also should ensure consistent application of GGP. Employees involved in the development, issuance, or application of significant guidance documents should be trained regarding the agency's GGP, particularly the principles of Section II(2). In addition, agency offices should monitor the development, issuance and use of significant guidance documents to ensure that employees are following GGP.

I have spoken to enough employees at all levels of the Office (including in the Office of the Assistant Commissioner for Examination Policy and Office of General Counsel, the two offices that would be most likely to be responsible for implementation), and I am reasonably certain that the PTO has never provided this training. Indeed, the only person I have ever talked to in the Office who is even aware of the *GGP Directive* is Jennifer McDowell, and she clearly lacks the authority to implement it.

E. If not now, when?

The effective date of the *GGP Directive* was July 24, 2007. It is long past time for the PTO to comply.

A search of the PTO's web site shows at least ten letters from several different parties requesting implementation of the *GGP Directive*.¹⁵ In September 2007, I personally asked John Love to implement it. I have left voice mails and similar informal communications with Robert Clarke and Robert Bahr seeking implementation. I have run the issue up through a Technology Center Director. In January 2010, I personally delivered a paper copy of the *GGP Directive* to David Kappos. All these requests have been met with silence.

To date, the only formal reply I have received was by Mr. Bahr dated November 3, 2010. I had specifically asked the PTO to implement the *GGP Directive*:

The PTO should implement the *Final Bulletin for Agency Good Guidance Practices* because it was duly issued by the Executive Office of the President under statutory authority, and it remains in effect. The PTO should not await specific intervention by OMB or the Department of Commerce.

In his reply, Mr. Bahr does not address my request at all. Rather, he notes irrelevantly that the forum for enforcement of the *GGP Directive* is not a federal court:

[The *GGP Directive*] expressly indicates that: "[t]his Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity, against the United States, its agencies, or other entities, its officers or employees, or any other person."

Mr. Bahr implies that the PTO will not comply with the *GGP Directive* unless and until compelled to do so by OMB or the Department of Commerce:

Any person may bring issues of alleged non-compliance on the part of the USPTO with [the *GGP Directive*] to the attention of the Department of Commerce or the Office of Management and Budget.

By copying this letter to Commerce Secretary Gary Locke and Office of Information and Regulatory Affairs Administrator Cass Sunstein, I am following Mr. Bahr's advice.

F. The *KSR Guidelines Update* violates the Paperwork Reduction Act

The *KSR Guidelines Update* alters the way examiners are expected to review patent applications. It thus necessarily follows that the *KSR Guidelines Update* also alters how applicants are expected to prosecute patent applications. Leaving aside the merits of the *KSR Guidelines Update*, there can be no doubt that the *Update* is a "material change to a collection of information"¹⁶ and therefore triggers PTO obligations under the Paperwork Reduction Act. The Paperwork Reduction Act defines *burden* broadly:

¹⁵ I am aware of other letters that do not show up in this search.

¹⁶ 44 U.S.C. § 3507(e)(1).

(2) the term "burden" means time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for--

- (A) reviewing instructions;
- (B) acquiring, installing, and utilizing technology and systems;
- (C) adjusting the existing ways to comply with any previously applicable instructions and requirements;
- (D) searching data sources;
- (E) completing and reviewing the collection of information; and
- (F) transmitting, or otherwise disclosing the information;...¹⁷

OMB's implementing rule expands upon this definition to make clear that there are no loopholes:

(b)(1) *Burden* means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency, including:

- (i) Reviewing instructions;
- (ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;
- (iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information;
- (iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;
- (v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;
- (vi) Training personnel to be able to respond to a collection of information;
- (vii) Searching data sources;
- (viii) Completing and reviewing the collection of information; and
- (ix) Transmitting, or otherwise disclosing the information.¹⁸

The new burdens resulting from the *KSR Guidelines Update* are subject to procedures set forth in the Paperwork Reduction Act.¹⁹ The *KSR Guidelines Update*

¹⁷ 44 U.S.C. § 3502(2).

¹⁸ 5 C.F.R. § 3503. Clause (b) exempts from the definition of burden the "time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities," provided that "the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary." This exemption does not apply to the burdens associated with patent applications, which but for the PTO's rules and procedures, no entity would ever endure.

¹⁹ 44 U.S.C. § 3506(c), as implemented by 5 C.F.R. § 1320.10 ("Clearance of collections of information, other than those contained in proposed rules or in current rules").

does not even mention the Paperwork Reduction Act or the incremental burdens it will impose. This is especially problematic given that the Paperwork Act prohibits the PTO from collection information without a valid OMB Control Number, which the PTO cannot obtain without complying with these procedures.

It is not clear at this time whether these incremental burdens can be predicted to be small or large. Nonetheless, it is the PTO's statutory duty under the PRA to objectively assess these burdens and follow the established procedures for seeking public comment on its estimates.

II. The disclaimer of supervisory responsibility is problematic, as is the open-ended discretion in creating new tests for obviousness

A. The Disclaimer of Supervision or Enforceability is inconsistent with multiple provisions of administrative law

The opening paragraphs of the *KSR Guidelines Update* state as follows (sentence numbers added):

... [1] This 2010 *KSR Guidelines Update* does not constitute substantive rule making and hence does not have the force and effect of law. [2] It has been developed as a matter of internal Office management and is not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. [3] Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. [4] Consequently, any failure by Office personnel to follow this 2010 *KSR Guidelines Update* is neither appealable nor petitionable.

These four sentences are simply wrong as a matter of administrative law.

1. The disclaimer paragraph leads to immense inefficiencies for both applicants and the Office

First, this paragraph misses the big picture: applicants have both substantive rights arising under § 102 *et seq.* of the Patent Act, *and* the right to regular, enforceable *procedure* during examination, rights arising under administrative law and 35 U.S.C. §§ 2 and 3. If an examiner skips a step in the *KSR Guidelines Update*, or makes up an alternative analysis that conflicts with or has no basis in the *KSR Guidelines Update*, the PTO is required to “manage and direct” during §§ 131/132 examination to get proceedings back on track. Yet this disclaimer appears to free PTO management of this core responsibility.

A refusal to compel examiners to honor these procedural rights causes immense harm to applicants, *and also to the PTO itself*. Harm to applicants is obvious: when the PTO's actual practices are unpredictable or random, the prosecution of patents is more expensive than it needs to be and some inventions are not patented because of these higher costs. For the PTO, the refusal to consistently honor or enforce procedure leads to random examination outcomes, which in turn leads to avoidable re-work. It is my

hypothesis (which the PTO has sufficient data to test) that a huge fraction of the PTO's backlog arises from rejections that were raised outside the bounds of procedure set by MPEP Chapter 2100, and which the examiner refused to reconsider despite written MPEP instructions. Far too many examiners disregard MPEP Chapter 2100 because they know that procedure will not be enforced, and that they will get their "counts" whether they carefully follow procedure or not. Examiners have only the incentive of personal ethics to write the showings that would result in clear Office Actions (or allowances) that would most efficiently advance prosecution.

2. The disclaimer paragraph is inconsistent with the PTO's obligations under administrative law

Second, sentence [1] has a kernel of truth, that instructions to *examiners* in a guidance document directed to *examiners* are not "substantive rulemaking" directed at the public and "do not have force of law" against the public. This is a straightforward application of 5 U.S.C. § 552(a) (with exceptions not applicable here, agency staff manuals may not be enforced against the public) and § 553 (rules are not enforceable against the public unless promulgated by certain procedures). Rather than "rules," examination guidelines are "regulation[s] for the government of [an Executive] department" under 5 U.S.C. § 301, a "staff manual" under 5 U.S.C. § 552(a), and an "economically significant guidance document" governed by the *GGP Directive*.

However, sentence [1] reflects the PTO's general lack of familiarity with basic administrative law terms of art. A non-substantive rule—that is, a procedural rule—*can* have "force of law" if validly promulgated, enforceable up to the point of forcing an application into abandonment.

In contrast, sentence [2] cannot be true. Where PTO guidance says examiners *shall* or *must* do y in response to x, the public is entitled to expect this to actually happen.²⁰ Thus, guidance does give the public a procedural benefit. To deny this is to assert that examiners have authority to act lawlessly. Sentence [4] also is wrong. The PTO cannot simultaneously commit examiners to act in certain predictable ways but disclaim any management responsibility to ensure that they do so. Because of sentence [4], many examiners will conclude that they are free to ignore the MPEP's instructions on the law to be applied and the findings that must be set forth in written decisions.

These common sense conclusions flow from a number of principles of administrative law that are routinely overlooked by the Office of Patent Examination Policy.

²⁰ *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967); 35 U.S.C. § 2(b)(3)(B) ("The Director shall—define the title, authority, and duties of such officers and employees and delegate to them such of the powers vested in the Office as the Director may determine.").

a. The statutory obligation to “manage and direct *all* activities” leaves no room for exceptions

PTO management is charged by statute to “manage and direct *all* activities” relating to patents, and to ensure that examination is carried out in a “fair, impartial, and equitable manner.”²¹ Sentences [2] and [4] disclaim any “management or direction” of examination for obviousness, which is contrary to law. A statute that says “all” means “all.”

b. Managing without clear legal direction is an abdication of management responsibility.

The President has directed agencies to provide clear and reasonably complete statements of the law to their employees in guidance documents:²²

§ 1(b)(12) Each agency shall draft its regulations and guidance documents to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

§ 2(a) *The Agencies*. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and guidance documents and assuring that the regulations and guidance documents are consistent with applicable law, the President’s priorities, and the principles set forth in this Executive order.

Through the denial of responsibility in the opening paragraphs of the *KSR Guidelines Update*, the PTO implicitly claims an exemption from this presidential directive, which has been in place for more than 17 years. This directive is not obsolete; President Obama recently reaffirmed it.²³

²¹ 35 U.S.C. § 3(b)(2)(A) (Commissioner for Patents shall be “responsible for the management and direction of all aspects of the activities of the Office that affect the administration of patent ... operations”); 35 U.S.C. § 131 (“The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.”); 35 U.S.C. § 3(a)(2)(A) (“The Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents ... The Director shall perform these duties in a fair, impartial, and equitable manner.”).

²² Executive Order 12,866, 58 Fed. Reg. 51735. President Obama revoked Executive Order 13,422 on January 30, 2009, so formal OMB review is limited to “regulatory actions” as defined in Executive Order 12,866 § 3(e).. However, the President did not direct OMB to rescind the *GGP Directive*. It remains in effect.

²³ Executive Order 13,563, 76 Fed. Reg. 3821, § 1(b): “This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993.”

c. Guidance cannot overrule regulation.

Sentence [4] is an attempt to use guidance to override a formal regulation. 37 C.F.R. § 1.181(a)(1) explicitly provides that there is no such thing as an examiner action that is “neither appealable nor petitionable”:

Petition may be taken to the Director .. [f]rom any action or requirement of any examiner in the *ex parte* prosecution of an application, or in the *ex parte* or *inter partes* prosecution of a reexamination proceeding which is not subject to appeal to the Board of Patent Appeals and Interferences or to the court... (emphasis added).

The plain language of § 1.181(a)(1) bars the PTO from creating gaps between petitionable and appealable subject matter.²⁴ Therefore, an examiner’s failure to follow § 1.104 or MPEP Chapter 2100 instructions *must* be petitionable, and subject to management oversight. Examiners are like any other employees who interact with the public: management has a duty to confine employee misconduct, and cannot let examiners act as unaccountable free agents free from supervisory instructions, free to injure third parties without supervisory intervention.²⁵

The PTO’s analytical error is a failure to recognize that sentence [4] discusses two different agency actions: the specific contents of a decision and the procedures by which that decision was made.²⁶ Substantive “rejection” is one agency action; and the

²⁴ The existence of appeal on the merits to the Board does not diminish the PTO’s duty to provide review for breaches of procedure at the examiner level. “Where the liberties of the citizen are involved, we said that ‘we will construe narrowly all delegated powers that curtail or dilute them.’” *Gutknecht v. U.S.*, 396 U.S. 295, 306-07 (1970). The necessity of agency compliance with its own procedures, and the necessity of reviewability for departure from written procedure (despite the existence of or foreclosure of review on the merits), is often restated by the Supreme Court and lower courts. See footnote 28.

²⁵ 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.”); *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 376–77 (1998) (“Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the [agency] must be required to apply in fact the clearly understood legal standards that it enunciates in principle... Reviewing courts are entitled to take those standards to mean what they say...”).

²⁶ 5 U.S.C. § 551(13) (“‘agency action’ includes the whole or a part of an agency rule, order, ... relief, or the equivalent or denial thereof, or failure to act”); *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986) (drawing distinction between “challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves,” emphasis the Supreme Court’s, two separate actions with two different paths of review).

It is commonplace that a single body of facts or single agency decision may embody separate “agency actions,” 5 U.S.C. § 551(13), with corresponding separate claims for relief

PTO correctly understands that this agency action is substantive and appealable. However, “failure by Office personnel to follow” instructions given by the agency head is a *separate agency action*, a procedural action that is not appealable.²⁷

under different bodies of law, and those claims for relief may require different proceedings in different fora. *E.g.*, *Federal Communications Comm’n v. NextWave Personal Communications*, 537 U.S. 293, 303–04 (2003) (bankruptcy proceeding on the merits originated in New York bankruptcy court, APA review of same facts originated in D.C. Circuit. The earlier case denied relief under bankruptcy, but the APA case resulted effectively in discharge of the debt, which the Supreme Court affirmed). Any notion that all issues relating to rejections of claims must necessarily all go to the same tribunal would have few if any analogies elsewhere in the law, and has no support in any known case from any appellate court.

²⁷ Many Board decisions recognize the “two separate actions” principle, and hold that examiner violation of procedural guidance is petitionable. The Board lacks jurisdiction to hear issues that “dispute the administrative processing of [a rejection alleged to be procedurally improperly raised during] the prosecution.” The Board insists that “the proper procedure is to seek review by way of petition...” *Ex parte Edwards*, Appeal No. 98-1396, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&filNm=fd981396> at 4, 1998 WL 1736081 at *2 (BPAI Apr. 27, 1999) (non-precedential); *Ex parte Dutton*, Appeal No. 2009-014442, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&filNm=fd2009014442-09-10-2010-1> at 7, 2010 WL 3803762 at *3 (BPAI Sep. 10, 2010) (unpublished) (“Dutton complains that the Examiner failed to follow guidelines set out in the Manual of Patent Examining Procedure (“MPEP”). The MPEP, however, provides guidance for Examiners: ... Failure to comply with guidance is not *per se* appealable to the Board, as the jurisdiction of the Board is limited to review of rejections. Relief regarding the conduct of the examination must be sought via the supervisory chain of authority over the Examiner.”); *Ex parte Franklin*, Appeal No. 2009-010199, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&filNm=fd2009010199-09-29-2009-1> at 21, 2009 WL 3151080 at *10 (BPAI Sept. 29, 2009) (unpublished) (“We do not superintend the manner in which examiners carry on prosecution or conduct patent examination. If Poly was dissatisfied with the Examiner’s treatment of the [reply] to the Final Rejection, then Poly should have called that matter to the attention of the Examiner. In the event of an unlikely unacceptable response from the Examiner, Poly’s avenue of relief was a petition.”); *Ex parte Hottovy*, Appeal No. 2008-4938, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&filNm=fd20084938-03-24-2009-1> at 22–23, 2009 WL 798882 at *11 (BPAI Mar. 24, 2009) (unpublished) (“As a first matter, we note Appellants take issue with the manner in which the Examiner has conducted the examination [for obviousness]. ... Appellants should address their concerns in a petition to the Director of the USPTO under 37 C.F.R. § 1.181. ... The Director, rather than the Board, has supervisory authority over Examiners.”). In its decisions, the Board has often reiterated that “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/bpaifag.htm>; *Ex parte Gambogi*, 62 USPQ2d 1209, 1212 (BPAI 2001) (“We decline to tell an examiner precisely how to set out a rejection”). Once the Board holds that an issue is not appealable, 37 C.F.R. § 1.181(a)(1) requires that it be petitionable.

d. Agencies are obligated to follow their own procedures.

The *prima facie* tests set out in MPEP Chapter 2100 are precisely the kind of “procedural” rules for agency self-regulation that the agency is obligated to follow and enforce, and that the Supreme Court has held are almost never exempt from review.²⁸ “Neither appealable nor petitionable” in sentence [4] violates the Supreme Court’s statement of the law.

e. Nonexistent statutory powers cannot be exercised, so they cannot be delegated.

Under basic common law agency principles, the Director cannot delegate to examiners authority that the Office itself lacks.²⁹ The Patent Office, the Director, and the Commissioner all lack the authority to reject claims without making limitation-by-limitation *prima facie* showings required by Title 37 C.F.R., Chapter 5 of the APA, and Federal Circuit authority, and the MPEP where it consists of legally permissible guidance and not impermissible regulation in disguise.³⁰ The Patent Office cannot grant greater authority to examiners than the Patent Office itself has.

²⁸ *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 672 n.3 (1986) (“Only in the rare—some say non-existent—case ... may review for ‘abuse’ be precluded”); *Fort Stewart Schools v. Federal Labor Relations Auth.*, 495 U.S. 641, 654 (1990) (“It is a familiar rule of administrative law that an agency must abide by its own regulation.”); *Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (“Where the rights of the individuals are affected, it is incumbent upon agencies to follow their own procedures.”); *Vitarelli v. Seaton*, 359 U.S. 535, 546-47 (1959) (Frankfurter, J. concurring) (“An executive agency must be rigorously held to the standards by which it professes its action to be judged. Accordingly, if dismissal from employment is based on a defined procedure, ..., that procedure must be scrupulously observed.”); *Service v. Dulles*, 354 U.S. 363, 371-73, 388 (1957) (agency must comply with its own regulations, and court has jurisdiction to consider claims that it did not do so); *Reuters v. F.C.C.*, 781 F.2d 946, 950-51 (D.C. Cir. 1986) (“Ad hoc departures from [an agency’s] rules, even to achieve laudable aims, cannot be sanctioned.”); *Peoples v. United States Department of Agriculture*, 427 F.2d 561, 567 (D.C. Cir. 1970) (“[T]he general rule, subject only to rare exceptions, [is] that the action of a government agency ... is subject to judicial review for arbitrariness and abuse of discretion even though discretion may be broad.”).

²⁹ Restatement (Agency) 2d §§ 213(c), 214.

³⁰ *E.g.*, in *Gechter v. Davidson*, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997), the Federal Circuit explained the PTO’s procedural obligations as follows:

In sum, we hold that the Board is required to set forth in its opinions specific findings of fact and conclusions of law adequate to form a basis for our review. In particular, we expect that the Board’s anticipation analysis be conducted on a limitation-by-limitation basis, with specific fact findings for each contested limitation and satisfactory explanations for such findings.³ Claim construction must also be explicit, at least as to any construction disputed by parties to the interference (or an applicant or patentee in an *ex parte* proceeding).

3. In other contexts, the PTO has recognized its duties.

In the recent Federal Circuit oral argument in *In re Jung*, App. 2010-1019 (Nov. 2, 2010), the Solicitor opened his argument as follows:

Patent prosecution is an interactive process. The Examiner goes first. Under § 132, the examiner *has an obligation* to put the applicant on notice as to *precisely* what the rejection is, and to do so well enough so that the applicant *knows* how to respond. ... The examiner has to point specifically enough to the *exact part of the reference* that the examiner thinks is within the scope of the claims and must do so clearly enough so that the applicant *knows what to do*, so that the applicant isn't shooting arrows into the dark. That's what *In re Oetiker* refers to.

Unfortunately, the Solicitor's assurance to the court states accurately PTO's legal obligations but not its actual practice, which is reflected in sentence [4]. All too often (and perhaps specially in 3690, and 3710), what the Solicitor said PTO does is precisely what *doesn't* happen. All too often, examination managers believe they have no obligation to enforce the procedural rules in Chapter 2100 of the MPEP. For example, recent petitions decisions state that examiners' actions are not required to set out limitation-by-limitation comparisons of claims to the art.³¹ Management's refusal to enforce the requirements of Chapter 2100 is a major factor in the PTO's backlog.

B. The open ended grant of examiner discretion should be reversed.

The preamble to the *GGP Directive* urges agencies to provide guidance to their employees that improves efficiency by channeling employees' discretion:

Agencies may provide helpful guidance to interpret existing law through an interpretive rule or to clarify how they tentatively will treat or enforce a governing legal norm

³ ...[O]bviousness determinations, when appropriate, similarly must rest on fact findings, adequately explained, for each of the relevant obviousness factors in the Supreme Court's decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), and its progeny in this court.

³¹ *E.g.*, Acting Assistant Commissioner Robert Bahr, Decision on Petition to Withdraw Premature Final Rejection, 09/385,394 at page 12 (June 21, 2010) ("Petitioner should be advised that there is no requirement that an element for element or limitation for limitation identification between the claims and reference(s) be provided to applicant ... in the examination process"). But compare *Gechter v. Davidson*, quoted in footnote 30; *In re Rouffet*, 149 F.3d 1350, 1355, 1359, 47 USPQ2d 1453, 1455, 1459 (Fed. Cir. 1998) ("To reject claims in an application under section 103, an examiner must **show** an un rebutted *prima facie* case of obviousness., emphasis added); *In re Oetiker*, 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447 (Fed. Cir. 1992) ("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. The '*prima facie* case' notion ... seemingly was intended to leave no doubt among examiners that they must state clearly and specifically any objections (the *prima facie* case) to patentability, and give the applicant fair opportunity to meet those objections with evidence and argument," citations and quotations omitted) (Plager, J., concurring).

through a policy statement. Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties.³²

But the *KSR Guidelines Update* creates what many examiners will misconstrue to permit any subjective sense of obviousness to be a sufficient ground to reject claims:

However, the *2007 KSR Guidelines* also stressed that while the *Graham* inquiries and the associated reasoning are crucial to a proper obviousness determination, the Supreme Court in *KSR* did not place any limit on the particular approach to be taken to formulate the line of reasoning. In other words, the *KSR* decision is not to be seen as replacing a single test for obviousness—the TSM test—with the seven rationales listed in the *2007 KSR Guidelines*....³³

This open ended grant of discretion allowing examiners to invent their own reasoning will create great inefficiency for both the Office and for applicants, and increase rather than diminish the PTO's pendency problem. Read in combination with the PTO's denial of supervisory responsibility, examiners will not be held accountable for failing to follow the PTO's instructions. When examiners are not held accountable, abuses and unpredictable examination are likely.³⁴ When applicants have no means to enforce procedurally-correct and complete examination, prosecution will drag on, be more expensive than necessary for the applicant and for the Office, and deprive applicants of rights to which they are entitled. The PTO should follow and enforce the *procedural* and *administrative* law, and carry out its obligation to ensure examiner compliance with guidance, so that applicants and examiners can proceed from a common set of assumptions, and under predictable procedures.

To correct this defect, the *KSR Guidelines* should be revised as follows:

- The Office Action must show that all elements are known or suggested in the art. The examining corps need to be reminded that “suggested” requires some affirmative statement in a reference pointing specifically in the direction of the claim element.³⁵ After an examiner identifies a claim element that is absent from the art, it is *never* allowable to create it by examiner reasoning (except for the “species within disclosed genus” of MPEP § 2144.08). All tests for obviousness require, at the least, that all elements be known.
- The Office Action must make some showing corresponding to “motivation to combine,” whether that showing is designated “use of known technique to

³² *GGP Directive* at 3432.

³³ *KSR Guidelines Update* at 53644/3 to 53645/1.

³⁴ See, e.g., 09/611,548, Office Action of Nov. 1, 2006.

³⁵ One examiner maintained that disclosure of “anything under the sun” made all species obvious. 10/879,972, Action of March 4, 2008, examiner maintains on final, Jan. 9, 2009,

improve similar devices,” “improve similar devices,” “ready for improvement to yield predictable results,” “design need or market pressure,” design incentives or other market forces, or the like—all of the *KSR* tests include some corresponding showing.

- The Office Action must make some showing corresponding to “reasonable expectation of success,” whether that showing is designated “predictable results,” “predictable solutions,” “anticipated success”, “variations [that] are predictable to one of ordinary skill in the art,” or the like—all of the *KSR* tests include some corresponding showing.
- Each of the above three points must be based on substantial evidence—an examiner may *explain* substantial evidence, but may not create facts out of hindsight.
- The *KSR Guidelines* should make clear that while *KSR* did not purport to state all possible tests for obviousness, the range of variations is very narrow, and individual examiners lack authority to coin new tests for obviousness.³⁶ The *KSR Guidelines* should state clear boundaries on the scope of tests that may be used. Since all of the Supreme Court’s *KSR* tests are variations on the “all elements known, motivation to combine, reasonable expectation of success” theme, the *KSR Guidelines* should confine examiners’ discretion to at least that degree.

III. In the interest of efficiency and reducing backlog, the PTO should curtail or rescind Official Notice

The Office could significantly improve efficiency of examination for obviousness by rescinding MPEP § 2144.03(C) and sharply limiting authorization to rely on Official Notice. Official Notice is only permissible when the fact is “capable of instant and

³⁶ For a few examples of the trouble that the current *Guidelines* cause, by failure to set any bounds on examiners’ discretion to coin personal tests for obviousness, see:

- 10/127,226, Action of June 8, 2010—the Action spends four pages explaining why the examiner resists using any of the *KSR*/MPEP § 2143 rationales, but instead grants himself authority to use short-cuts that are clearly not within the scope of discretion that the PTO intended to grant.
- 10/983,279—the Action of April 14, 2010 states that a claim is obvious unless the application discloses an “advantage, use for a particular purpose, or solves a stated problem.”
- “Changes to the prior art yielding predictable results are considered obvious.” 10/879,972, Action of March 1, 2010.
- “Matter of obvious design choice” was advanced as a permissible test for obviousness in 10/879,972, Action of March 1, 2010.
- Disclosure of “an infinite number of ways” makes certain specific species obvious, 10/879,972, Final Action of Jan. 9, 2009.

unquestionable demonstration.” “Instant,” by definition, means that all permissible assertions of official notice represent a time savings of essentially zero for the examiner. Thus, every correct assertion of Official Notice has almost no benefit, and every incorrect assertion of Official Notice creates considerable costs for both the applicant and the examiner. The overwhelming majority of all assertions of Official Notice do not satisfy the requirement of “instant and unquestionable” demonstrability, and are thus wrong and needlessly costly. In fact, at least in 3690 and 3710, the overwhelming majority of noticed “facts” of which I am aware are simply wrong—the impossibility of finding a reference to support a wrong statement is the reason that the examiner had difficulty locating a supporting reference and relied instead on Official Notice. Official Notice simply leads to disputes that should not have arisen. The consequent delays and costs benefit neither the Office nor applicants.

There are two actions that the Office should take.

First, MPEP § 2144.03(C) should be removed. First, it inappropriately applies standards for court/court review to intra-agency proceedings, a problem I have noted several places elsewhere in this letter. Second, the requirement for an applicant to show “reasonable doubt” is a shift of the burden of proof, which makes MPEP § 2144.03(C) a substantive rule³⁷ and thus outside the PTO’s rule making authority. Third, § 2144.03(C) was added to the MPEP without observance of the rulemaking procedure required by 35 U.S.C. § 2(b)(2)(B), 5 U.S.C. §§ 552(a), 553, and 603, 44 U.S.C. §§ 3506 and 3507, and without prior review under Executive Order 12,866. In short, § 2144.03(C) is illegal on multiple levels and its illegality cannot be cured.

Second, the PTO should make *very* clear to examiners that Official Notice may *only* be relied on with a showing of “explicit basis,” that not rational disagreement among reasonable men is possible.

Third, MPEP § 2144.03 should explicitly remind examiners of 37 C.F.R. § 1.104(d)(2), which unconditionally requires that the examiner come forward with substantial evidence if the applicant merely “calls for” it. The PTO cannot attenuate § 1.104(d)(2) by the MPEP.

³⁷ *Director, Office of Workers’ Compensation Programs, Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267, 271, 275–81 (1994) (“[T]he assignment of the burden of proof is a rule of substantive law.”); *Fabil Mfg. Co. v. United States*, 237 F.3d 1335, 1341 (Fed. Cir. 2001) (Customs Service lacks authority to set burdens of proof; “that task is for the judiciary or the Congress”); *Tafas v. Dudas*, 541 F.Supp.2d 805, 817, 86 USPQ2d 1623, 1632 (E.D. Va. 2008) (“by requiring applicants ... to perform prior art searches and by shifting the examination burden away from the USPTO, the ESD requirement [of the 5/25 Claims Rule] manifestly changes existing law and alters applicants’ rights under Sections 102, 103, and 131. Applicants must now undertake new substantive responsibilities ... For these reasons, the Court finds that Final Rules 75 and 265 are substantive rules.”), *rev’d Tafas v. Doll*, 559 F.3d 1345, 90 USPQ2d 1129 (Fed. Cir. 2009), *district court decision reinstated sub nom. Tafas v. Kappos*, 586 F.3d 1369, 1371, 92 USPQ2d 1693, 1694 (Fed. Cir. 2009).

Fourth, MPEP § 2144.03 should make clear that a second action may not be final if either:

- the “explicit basis” was omitted from the earlier action, or
- a new reference is provided to support the assertion of official notice.³⁸

IV. Two issues of claim interpretation should be clarified

A. “Wherein” clauses and “functional language”

MPEP § 2106(II)(C) and § 2111.04 include a list of alleged “examples of language that may raise a question as to the limiting effect of the language in a claim.” The list is incorrect, and should be revised as follows:

- (A) “statements of intended use” in claim preambles are not limiting under the “broadest reasonable interpretation” standard applied during examination. Language qualifies for the “intended use” exception if it expresses only a subjective intent of a human being, and by its grammatical form has no functional or practical effect on the structure or step being modified. A computer “designed to” or “configured to” has a structural limitation, not an intended use.
- (B) “Adapted to,” “adapted for,” and “capable of” clauses in the body of a claim are limiting to the extent that they impose some functional capability or limitation, but not when they only state a subjective intent. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1478, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997); *In re Venezia*, 530 F.2d 956, 959, 189 USPQ 149, 152 (CCPA 1976).
- (C) “Functional language” in a claim body (including statements of functional results) are always limiting, subject to (A) and (B), and the rule for “product-by-process” claims of MPEP § 2113. See, e.g., *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1350 (Fed. Cir. 1998).
- (D) “Whereby” and “thereby” clauses in the body of a claim are not given weight when the clause merely expresses the intended result of a process step positively recited, but are given weight in all other circumstances.

“Wherein” clauses (formerly item (C)) should be deleted from the list – “wherein” clauses are always limiting, except possibly when they fall within “statements of intended use” in preambles of item (A), but “wherein” clauses are not in themselves a separate class of non-limiting claim language. See, e.g., *Griffin v. Bertina*, 285 F.3d

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)

1029, 1033-34 (Fed. Cir. 2002) (distinguishing “whereby” and “wherein” clauses, and explaining that “wherein” clauses are not governed by the “thereby/whereby” rule). In a May 2009 email conversation with a member of the OPLA/MPEP staff, the PTO admitted “I am not aware of any case law holding that a “wherein” clause was not limiting...” Without some such case law, there is no reason to depart from the general rule: all claim language is limiting unless an established exception (preambles, “whereby” clauses, and a few others) applies. There are a number of cases in which “wherein” clauses are outcome-determinative, and I know of no case (only a defendant’s argument that was dismissively rejected by the court in *Griffin*) that even “raises a question.”³⁹ I believe that the MPEP’s statement that “wherein” clauses “may raise a question” is just plain wrong.

If there is some case law that I don’t know of that suggests that “wherein” clauses might not be limiting in some circumstance, then it’s crucial to give examiners guidance on the specific scope of the exception, and some standard that can be applied. The current MPEP provision, “may raise a question,” without any “articulable standard” for deciding the question raised, is illegally vague,⁴⁰ and creates immense costs.

B. The PTO should clarify and correct the MPEP’s description of “descriptive matter” in the context of § 102/103

The MPEP should be clarified that there is no “descriptive matter” exception for § 102/103 purposes, only “printed matter.” Though there is no authorization in the MPEP to disregard “descriptive matter,” examiners (especially in 3690) do it a lot; it wastes everyone’s time; and it is illegal.

³⁹ *Shanghai Meihao Electric Inc. v. Leviton Mfg. Co. Inc.*, 212 Fed. Appx. 977 (2007) (non-precedential) (finding non-infringement because “wherein activation of the reset device activates the circuit interrupter to be in the operational state” clause not satisfied); *Sunrace Roots Enterprise Co. v. SRAM Corp.*, 336 F.3d 1298, 1303, 67 USPQ2d 1438 (Fed. Cir. 2003) (“wherein” clause of a dependent claim given weight to construe an independent claim under the doctrine of claim differentiation); *In re Roemer*, 258 F.3d 1303, 59 USPQ2d 1527 (Fed. Cir. 2001) (reversing the Board, and holding claim 33 patentable because of a “wherein . . . the resultant magnetic field on the opposite side of the second coil to the first coil is substantially zero” clause); *In re Kotzab*, 217 F.3d 1365, 1370-71, 55 USPQ2d 1313 (Fed. Cir. 2000) (reversing the Board based on a “wherein” clause); *Ex parte Cifra*, <http://des.uspto.gov/Foia/ReterivePdf?system=BPAI&fINm=fd20071318-10-10-2007-1> (BPAI 2007); MPEP § 2111.03 *citing In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004) and MPEP § 2131.02, *citing In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).and MPEP § 2173.05(h)(II) giving examples of cases where “wherein” clauses are given dispositive weight.

⁴⁰ 44 U.S.C. § 3506(c)(3) (agency requests for information shall be “written using plain, coherent, and unambiguous terminology and . . . understandable to those who are to respond”).

The Federal Circuit has ordered that “descriptive” language must be given weight under § 102/103. For example, *In re Lowry*, 32 F.3d 1579, 1582-83, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994), states (emphasis added):

The Patent and Trademark Office (PTO) must consider all claim limitations when determining patentability of an invention over the prior art. ... The PTO may not disregard claim limitations comprised of printed matter. ... A ‘printed matter rejection’ under § 103 stands on questionable legal and logical footing. ... [The Court of Customs and Patent Appeals], notably weary of reiterating this point, clearly stated that printed matter may well constitute structural limitations upon which patentability can be predicated.”

and *In re Gulack*, 703 F.2d 1381, 1384-85, 217 USPQ 401, 403 (Fed. Cir. 1983) (emphasis added):

Differences between an invention and the prior art cited against it **cannot be ignored** merely because those differences reside in the content of the printed matter. ... **[T]he board cannot dissect a claim, excise the printed matter from it, and declare the remaining portion of the mutilated claim to be unpatentable.** The claim must be read as a whole.

Lowry goes on to explain that any residual applicability of the “printed matter” exception is confined to “arrangements of printed lines or characters, useful and intelligible only to the human mind,” such as cases involving adding instruction manuals in kits.

V. The Guidelines should include a checklist of findings that are required, and analytical steps that are forbidden

The Guidelines should include a checklist of findings that *must* be in every written obviousness rejection: It would be worthwhile to include a checklist much like this in Form PTOL-326 (Office Action Summary) as a reminder that every action must be complete, 37 C.F.R. § 1.104(a):

- 37 C.F.R. § 1.104(c)(2) has two separate requirements: designate particular parts relied on “as nearly as practicable,” and ‘clearly explain’ pertinence. This has several components:
 - All obviousness rejections must include a limitation-by-limitation mapping to the prior art.⁴¹ The Office Action must consider the claim limitation-by-limitation. Paragraph-by-paragraph is insufficient.
 - Unless there is no conceivable ambiguity, the mapping must identify a specific item in the reference by name or reference numeral. A designation of a chunk of text, in hopes that the applicant can reconstruct the examiner’s thinking, is insufficient. The common practice in 3690 and

⁴¹ *Gechter v. Davidson*, 116 F.3d 1454, 1460, 43 USPQ2d 1030, 1035 (Fed. Cir. 1997).

3710, of designating large chunks (sometimes over a page), with a wish of good luck to the applicant to reconstruct the examiner's thinking, is not sufficient.

- Incidentally, the Office would do well to publish Pre-Grant Publications in column and line number format – the paragraph number format has led to a noticeable decline in care and precision in examiners' consideration of references.
- When an applicant makes a request for a reference or affidavit under 37 C.F.R. § 1.104(d)(2), the examiner must come forward with one or the other (or else a showing that the item requested is a legal conclusion rather than a fact). Commonly, at least in 3690 and 3710, examiners either totally ignore such requests, or give a more emphatic and longer explanation based solely on examiner opinion. Neither is permissible.
- The list of items from § II.B at page 19, limiting examiners' discretion to improvise new tests for obviousness, belongs here as well.
- The obligation to “answer all material traversed” is absolute.⁴²

The Guidelines should also include a list of steps and findings that are never permitted:

- It is *never* allowable to use the phrase “because it would have been obvious” within an obviousness rejection. The law nowhere authorizes circular reasoning. Obviousness is established by showing all *prima facie* elements: all elements, motivation, success. “Obvious because it would have been obvious” has no place in any Office Action.
- “Inherency” is applicable in anticipation, but plays only a limited role in obviousness. “Inherency” may never be relied on to meet direct claim language.

⁴² 5 U.S.C. § 555(e) (agency decision must include a “brief statement of grounds”); *Mulloy v United States*, 398 US 410, 418 (1970) (“Since the petitioner presented a nonfrivolous, *prima facie* claim for a change in the [agency decision] based on new factual allegations which were not conclusively refuted by other information in his file, it was an abuse of discretion for the board not to reopen [the decision], thus depriving him of his right to an administrative appeal.”)..

The “answer” must genuinely advance prosecution by either providing information to resolve a dispute, or make the dispute clearer so that it can be properly appealed. An example of what should *not* be permitted is in 10/150,476 the Action of January 20, 2010, which responds to a traverse with nothing more than that “The Examiner respectfully disagrees.” This does not advance prosecution.

VI. Procedural gate keeping

A. Procedural guidelines for obviousness should be enforced at several stages

Petitions for Premature Final Rejection and Pre-Appeals, should enforce examination procedure. At least in 3690 and 3710, SPE's apparently do not grant Pre-Appeals for "omissions of one or more essential elements needed for a *prima facie* rejection" as permitted by the 2005 O.G. notice.⁴³

Often, the omission of a *prima facie* element makes it impossible to frame a meaningful appeal—it's impossible to tell whether the dispute relates to

- claim interpretation?
- the content of the reference?
- some other fact—typically *Graham* secondary considerations?⁴⁴
- whether the reference is or is not prior art?
- the applicable law?
- application of the law to the facts?

Applicants need to know the precise basis for disagreement, so that they can identify whether the appropriate reply is

- a claim amendment,
- an argument,
- a cite to a Federal Circuit case, or
- a fact declaration.

The solution is simple, and was described by the Solicitor in his recent argument to the Federal Circuit *In re Jung*, which I quoted at page 18: now that the PTO has made the representation to the Federal Circuit that the PTO requires its examiners to identify grounds of rejection "*precisely*," and with sufficient precision so that applicants "*know*" what to do, the PTO must either take action to keep its promise to the Federal Circuit, or face the repercussions of taking positions in the *KSR Guidelines* that

⁴³ Joseph Rolla, New Pre-Appeal Brief Conference Pilot Program § 4, 1296 Off. Gaz. 67 (July 12, 2005), <http://www.uspto.gov/web/offices/com/sol/oq/2005/week28/patbref.htm> ¶ 4.

⁴⁴ *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18, 148 USPQ 459, 467 (1966) ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.").

contradict the PTO's representations to that court. When examiners fail to provide clear, complete Actions, it almost always reflects incomplete consideration of the claims. The claim limitations that are not carefully mapped to the prior art are often the very limitations that should have resulted in allowance. In other cases, where the rejection is substantively correct but procedurally incomplete, the applicant is left with an inscrutable statement and is unable to fully respond. In either case, procedural incompleteness of examiner written work product leads to immense loss of efficiency. My experience suggests that there has been a general decline in the quality of Office Actions since 2003, and that this decline in precision is the dominant cause of the increase in backlog, RCE's and Appeals.

The PTO should issue a memorandum to examiners, and make it available to the public, reminding them that careful, limitation-by-limitation comparison to the claims is essential and is a non-waivable requirement. Similarly, consideration of all *prima facie* elements of obviousness is essential and non-waivable. Examiners are permitted (in a procedural sense) to be incorrect, but they are never permitted to be silent. The memo should make *absolutely* clear that supervisory personnel have *no* discretion to waive procedural requirements, except through the formal waiver process contemplated by the *GGP Directive* (which to date the PTO lacks). Appropriate points to enforce observance of procedure include:

- requests for corrected Actions under MPEP § 710.06
- interviews with SPE's
- Pre-Appeals, which should reopen if there is an "omission of one or more essential elements needed for a *prima facie* rejection"
- Petitions to request enforcement of examination procedure, and to withdraw premature final rejection.

B. Pre-Appeal decisions must comport with 5 U.S.C. § 555(e)

Pre-Appeal is one of the natural points in the process to enforce procedural requirements.⁴⁵ However, it fails that function because current practice is to deny Pre-Appeals with only an unexplained "X" in a checkbox. This is insufficient to meet the PTO's obligations under 5 U.S.C. § 555(e). Both the law and concerns for efficiency mandate that, especially where the examiner has breached procedure by not fully stating positions on every element of a *prima facie* case, or has failed to answer all material traversed, a Pre-Appeal decision must "fill in the blanks." If that results in a "new ground of rejection," then prosecution must be reopened procedurally, even if the substantive rejection is maintained.

⁴⁵ Rolla, Pre-Appeal Memorandum, footnote 43 ("omissions of one or more essential elements needed for a *prima facie* rejection" is a proper ground for pre-appeal).

The Supreme Court requires that agency decisions give a statement of grounds that “examine[s] the relevant data and articulate[s] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.”⁴⁶ Lower courts have elaborated:⁴⁷

A “fundamental” requirement of administrative law is that an agency “set forth its reasons” for decision; an agency’s failure to do so constitutes arbitrary and capricious agency action. That fundamental requirement is codified in section 6(d) of the APA, 5 U.S.C. § 555(e). Section 6(d) mandates that whenever an agency denies “a written application, petition, or other request of an interested person made in connection with any agency proceeding,” the agency must provide “a brief statement of the grounds for denial,” unless the denial is “self-explanatory.” This requirement not only ensures the agency’s careful consideration of such requests, but also gives parties the opportunity to apprise the agency of any errors it may have made and, if the agency persists in its decision, facilitates judicial review. Although nothing more than a “brief statement” is necessary, the core requirement is that the agency explain “why it chose to do what it did.”

The DEA’s letter denying [the] petition ... does not meet the APA standard. The letter says nothing other than that the “Affidavit of Indigency you submitted in lieu of a cost bond is not adequately supported.” ... That is not a statement of reasoning, but of conclusion. It does not “articulate a satisfactory explanation” for the agency’s action, because it does not explain “why” the DEA regarded [the] affidavit as unsupported. Nor are the grounds for denying [the] application ... “self-explanatory,” 5 U.S.C. § 555(e), since the [agency stated no rebuttal to the petition’s showings of fact]. The letter thus provides no basis upon which we could conclude that it was the product of reasoned decisionmaking.

An unexplained “X” is insufficient to meet the PTO’s obligations.

⁴⁶ *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

⁴⁷ *Tourus Records Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736–37 (D.C. Cir. 2001) (citing *State Farm*, citations, quotations, and footnotes omitted); see also *Dr. Pepper/Seven-Up Companies Inc. v. Federal Trade Comm’n*, 991 F.2d 859, 864–65 (D.C. Cir. 1993) (agency’s “conclusory dismissal” that failed to consider key evidence and a key claim was “wholly inadequate” and “leaves too many questions unanswered to qualify as reasoned decisionmaking”); cf. *Dunlop v. Bachowski*, 421 U.S. 560, 571 (1975) (for Labor Management Reporting and Disclosure Act cases, “When action is taken by [the Secretary] it must be such as to enable a reviewing Court to determine with some measure of confidence whether or not the discretion, which still remains in the Secretary, has been exercised in a manner that is neither arbitrary nor capricious... [I]t is necessary for [him] to delineate and make explicit the basis upon which discretionary action is taken. ... Moreover, a statement of reasons serves purposes other than judicial review. ... [A] ‘reasons’ requirement promotes thought by the Secretary and compels him to cover the relevant points and eschew irrelevancies, and ... the need to assure careful administrative consideration ‘would be relevant even if the Secretary’s decision were unreviewable.’”).

Pre-Appeal procedure should be revised to require that appeal conferences give a “brief statement of grounds” for denying the request and for forwarding the appeal to the Board. This is not only necessary for compliance with the law, it will improve the quality of decision making. In my experience, a huge majority of all Pre-Appeal decisions affirming the examiner are subsequently reversed when the examiner is forced to carefully consider the issues in a written Examiner’s Answer. In recent years, about 80% of Appeal Briefs receive an allowance or reopen, rather than an Examiner’s Answer. The PTO’s data confirms my anecdotal impressions, that Pre-Appeal conferences generally give insufficiently careful consideration to Pre-Appeal briefs (especially procedural failures to address all *prima facie* elements). A requirement for written decisions would improve agency throughput.

VII. Conclusion

I am generally encouraged by fresh winds in the PTO over the last few months. In my comments, I have provided numerous ways the PTO can improve the *KSR Guidelines* by redoubling the Office’s attention to compliance with procedural law and enforcing internal procedures. Procedural law exists so that the public and agency know what to expect of each other, establishing (as the *GGP Directive* notes) clear guidance channeling the discretion of agency employees in ways that improve efficiency and reduce injustice.

Sincerely,

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