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From: Graciela Cowger [mailto:GracielaCowger@techlaw.com]

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To: AB93Comments; AB94Comments

Cc: Clarke, Robert; Rick Wilhelm; Phillips, Matthew; Gwynedd Warren

Subject: OPLA comments on the PTO's proposed rule changes

RE: Comments on Proposed Rules

"Changes to Practice for the Examination of Claims in Patent Applications"
71 Fed. Reg. 61 (January 3, 2006)

"Changes to Practice for Continuing Applications, Requests for Continued
Examination Practice, and Applications Containing Patentably Indistinct Claims"
71 Fed. Reg. 48 (January 3, 2006)

The Oregon Patent Law Association (OPLA) is a non-profit professional association of over 200 patent lawyers and others based primarily in Oregon and Southwest Washington. OPLA's mission is to provide a forum for communication and action in matters of common interest.

We appreciate the opportunity to provide our comments on the proposals as detailed in the attached Memorandum.

Graciela Cowger
Director

Marger Johnson & McCollom, P.C.
210 SW Morrison Street, Suite 400
Portland, OR 97204 USA
Phone: (503) 222-3613
Fax: (503) 274-4622
www.techlaw.com



Oregon Patent Law Association

MEMORANDUM

I. INTRODUCTION

The Patent and Trademark Office (PTO) proposes rule changes that broadly affect patent prosecution. The PTO published its proposed rule changes, together with their corresponding explanation and summary, in the Federal Register. 71 Fed. Reg. 48, 61 (03 January 2006). OPLA offers the following comments and objections on the proposed rule changes.

II. COMMENTS ON THE PTO'S PROPOSED CLAIM EXAMINATION RULE CHANGES

The PTO proposed rule changes that stipulate that applicants may identify up to ten representative claims for initial examination. The representative claims must include all of the independent claims, and if less than ten independent claims, additional designated dependent claims up to a total of ten.¹ If the application includes more than ten independent claims, or the applicant wishes to have initial examination of more than ten representative claims, then the applicant must provide an examination support document (ESD) that addresses all of the independent claims and the dependent claims designated for initial examination.

- The ESD must include a statement that a pre-examination search was conducted, and identify the search field by class and sub-class, date, database, logic, chemical structure or sequence, and like, and must be accompanied by an information disclosure statement (IDS) citing the references most closely related to the subject matter of the claims.
- The ESD must include a statement of utility for each independent claim and a showing that each limitation in the claims is supported in the specification.
- The ESD must include an identification of all the limitations of the independent claims and designated dependent claims that are disclosed by the references cited.
- The ESD must include a detailed explanation of how each of the independent claims and designated dependent claims are patentable over the references cited in the IDS.

1. ESDs pose unacceptable risks of inequitable conduct.

The proposed rule changes impose unacceptable risks with respect to charges of inequitable conduct on applicants and their agents. Under the proposed rule changes, an applicant would need to file an ESD whenever more than ten representative claims are identified for initial examination. The ESD notably requires an identification of which

¹ In the event that no representative claims are designated, the PTO will initially examine only the independent claims.

limitations each reference discloses and a detailed explanation of how each of the claims are patentable over the references cited in the IDS.

This requirement poses an enormous burden on both individual applicants and those represented by a designated agent. Many individual inventors will lack the skills to adequately search and evaluate identified references with respect to patentability. Providing a detailed explanation of how claims are patentable requires knowledge of patent law, and a reasonable basis for assessing not only anticipation but non-obviousness in often complex technological areas. In addition, many inventors will be unable to meet the substantial costs of obtaining a professional search and patentability opinion, many of which cost upwards of \$5,000-\$10,000.

Patent practitioners, while equipped with the professional skills necessary to search and assess patentability, will be faced with malpractice risks unparalleled under the current practice regime. To meet the ethical obligations of Rule 56, applicants and their agents must currently provide the Office only with notice and copies of *known* material references, and requires that the applicant (through his agent) not knowingly mischaracterize those references (or additional references identified by the examiner) by omission or false statements. An ESD escalates this requirement by requiring that previously unknown references be identified, and that their materiality with respect to patentability not only be ascertained but communicated on the record to the Office. Such a communication appears to be subject to the same strictures regarding intentional false statement or omission, with the more material the misstatement or omission, the more likely the inference of intent. While one can be very careful in characterizing two or three documents, cited by an examiner, when one responds to an Office action, it is not possible at reasonable expense to characterize copious documents identified in a search with a high level of care. Any time a search and analysis of references is performed in a technical area (many with extensive patent and non-patent literatures), there is a very real and substantial risk that a seemingly minor feature disclosed by a reference will be overlooked or misinterpreted, and that such errors will be later be found by a court to be material, and thus intentional. Thus, by forcing the undertaking of a search and characterization of the identified references, the proposed rules significantly increase the likelihood that applicant or agent errors will later be characterized as willful misconduct, which renders the patent unenforceable and leaves the practitioner open to charges of professional misconduct and/or legal malpractice. Furthermore, this burden will not be limited to the applicant and his or her agent, but will be propagated through the courts as increased claims for malpractice and charges of inequitable conduct will inevitably result.

Thus, such a change to the rules should not be imposed unless corresponding changes to the law and rules regarding inequitable conduct also be established to alleviate the burden to applicants, their agents, and the courts. This cannot be accomplished solely by changes to PTO Rule 56, as past experience has demonstrated that such rule changes are insufficient in the view of the courts. Rather legislative reform of the inequitable conduct doctrine is required to clarify the obligations and provide guidelines that are workable in view of the increased burden of ESD practice.

2. ESDs will significantly prejudice patentees in their attempts to enforce their patents

The filing of an ESD establishes a written record that burdens the applicant and benefits future infringers in future infringement litigation. Every explanation of how a claim is patentable over any piece of prior art will provide accused infringers with ammunition to argue for a narrow claim interpretation, as courts in their roles as claim construers, give special significance to applicants' statements in the prosecution history, which is intrinsic evidence for claim construction purposes. Also, by operation of the doctrine of argument-based estoppel, those explanations will also limit patentees' opportunity to make use of the doctrine of equivalents to an unprecedented degree.

3. Identification of representative claims will result in an increase in the number of applications filed

The proposed rule changes will result in a significant increase in the number of applications filed. Notwithstanding the proposed changes to the rules controlling the filing of multiple related applications with substantially overlapping disclosures, requiring applicants to file an ESD if more than ten claims are designated will cause applicants to avoid the necessity of filing an ESD by filing multiple applications with claims drawn to different aspects of the disclosure that the applicant views as likely to be restricted into separate applications. The additional cost in terms of filing fees is likely to be less than the cost of the search and patentability analysis required by the ESD, and is not accompanied by the negative consequences with respect to inequitable conduct or future litigation. Such multiple filings will increase the PTO's workload as well as the likelihood that related applications will be assigned to different examiners (and indeed to different art groups) rather than streamlining prosecution as intended.

4. Representative claim identification will lengthen not shorten examination

Identification of representative claims will not shorten prosecution, as suggested by the PTO. Rather identification and examination of representative claims will lead to a protracted sequence of limitation-by-limitation exchanges between the examiner and the applicant. Under current practice, applicants and their designated agents use feedback provided by the examiner regarding multiple claims with different limitations and scope to identify those particular limitations that the applicant and examiner agree constitute a patentable invention. A well-searched and articulated rejection addressing all of the claims allows an applicant to immediately identify those points of agreement, and disagreement with examiner, and to amend or direct arguments to overcome rejection and obtain allowable claims. Where limitations are presented in dependent claims, it is apparent from the first Office action which limitations are viewed as necessary by the examiner to overcome rejection. In many cases, and not rarely, more than ten distinct limitations or related sets of limitations are relevant to determining the precise scope of an allowable claim. Because non-designated dependent claims will not be initially examined under the proposed rule changes, a first Office action is unlikely to address all of the limitations upon which an allowable claim can be based since the number of relevant limitations frequently exceeds the permissible number of designated claims.

This is true, even if an applicant provides new designated claims in response to a restriction requirement in which a single independent claim defines an invention. Nine dependent claims are frequently insufficient to recite all of the features relevant to patentability. Under the proposed procedure, the applicant will be required to blindly propose amendments to include limitations that have not been previously evaluated by the examiner. In combination with the permissibility of making a rejection final when first articulated in response to an amendment, it is likely that in many applications an applicant will never have all of the limitations that contribute to a patentable invention examined.

5. Representative claim identification may have unexplored detrimental consequences

The PTO has not adequately explored the potential detrimental consequences associated with representative claim identification, including effects on prosecution history estoppel, claim interpretation, and patent validity. The proposed rule changes will likely increase the number of issues and their attendant complexity during already complex patent litigation. Of particular concern is the extent to which the courts will continue to presume valid dependent claims not examined during prosecution. The PTO must work collaboratively with the federal courts before forging ahead with rules that will increase the caseload of an already overburdened federal court system.

6. Representative claim identification should require changes to the fee structure

The current fee structure assumes that the PTO will fully initially examine all claims. In particular, the basic fee purchases an initial examination of up to 20 claims, including up to 3 independent claims. The PTO should reduce the basic examination fee to reflect that it will only initially examine ten representative claims.

III. COMMENTS ON THE PTO'S PROPOSED CONTINUATION RULE CHANGES

The PTO proposed rule changes would limit continued examination practice, including continuing applications and requests for continued examination (RCE). The proposed rules would require that second or subsequent continued examination filings, whether a continuation application, a continuation-in-part application, or an RCE, be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted.

1. Without clarification of the standard to be applied with respect to a showing that an amendment, argument or evidence "could not have been previously submitted" it is not possible to fully evaluate the consequences of the proposed changes to the rules.

The PTO has not adequately articulated the standard to be applied in determining whether an amendment, argument or evidence "could not have been previously submitted." The proposed rule changes do not adequately address the circumstances under which an applicant will be considered to have been able to submit an amendment, argument or evidence during prosecution. Most importantly, the proposed rule changes have not

indicated the circumstances in which an applicant when responding to a final rejection will have been deemed to have been able to submit the amendment, argument or evidence at an earlier stage of prosecution. For example, applicants frequently receive a rejection based on new grounds in a second Office Action that is made final. Entry of amendments and/or arguments is made contingent by the examiner on filing of an RCE. If this situation occurs in a continuation application, the applicant may have no opportunity “of right” to even respond to new grounds of rejection absent an appeal. The Office needs to clarify whether under the proposed rules an applicant can be foreclosed from responding to new grounds of rejection in a second or subsequent Office action made final, as this interpretation of the proposed rule changes will severely compromise the ability of applicants to pursue complete examination of their claims. Alternatively, it is likely that the Office can allay many legitimate concerns regarding the rule changes by stating categorically that an amendment, argument or evidence could not have been previously submitted any time that it is first submitted in a timely response to a rejection made for the first time on new grounds.

Similarly, once the Office has clarified the circumstances under which an amendment, argument or evidence “could not have been previously submitted,” the Office must clarify the nature and contents of a sufficient showing under the standard. Absent such clarification, it is not possible for applicants or the Patent Bar to fully evaluate the likely consequences of the proposed rule changes. The PTO has indicated informally in a town hall meeting that it would be sufficient to show that the new ground of rejection could not have been “anticipated.” However, the PTO has remained entirely silent on what is necessary to make it possible to anticipate a rejection. This is simply an unworkable standard.

2. Internal PTO reforms would do more to reduce backlog and improve quality than limiting the number of continuation applications

To the extent continuation practice causes backlog problems, the solution should not be unilaterally imposed on applicants. The PTO itself shares responsibility for the problem, and internal PTO reforms must be a part of any solution.

Several institutional factors bias both applicants and examiners to turn too quickly to continuations. From the applicant’s perspective, continuation practice, particularly the filing of an RCE, is often an efficient option when an applicant and examiner disagree about the patentability of an invention but there is a reasonably good prospect that the applicant and examiner can reach agreement after further dialogue. Indeed, filing a continuing application is presently much quicker, cheaper, and offers a more certain outcome than appeal in most cases. From the examiner’s perspective, continuation practice offers easy “counts” within the PTO’s internal production metric system, as filing of a continuation or RCE gives the examiner one disposal count and a relatively easy first action count compared to examining a new application. For this reason, examiners are quick to make final rejections, sometimes prematurely, and applicants have little reason to resist finality.

Sometimes the pressure to get an application to the final rejection stage, as well as the pressure to get first action counts, causes examiners to do an inadequate examination before the first action. This can take many forms: Failure to find the closest prior art, failure to completely understand the claimed invention (even failure to read the specification), failure to adequately study and understand the prior art references, failure to apply the best prior art of record in formulating a rejection, and failure to adequately explain the grounds of rejection. These problems seemingly become more frequent near the end of a fiscal quarter, when examiners are more prone to be scurrying to achieve their target count totals. When these flaws afflict a first action, the case is considerably more likely to get a second action that is made final on new grounds, as even slight amendments can be cited by the examiner as a reason to make final a rejection premised on new grounds.

Thus, while the present count-based production system offers the clear advantages of accountability and some measure of fairness among the examiner corps, it must be recognized that this system also creates an internal institutional bias in favor of poor examination (particularly at the first action), final rejections, and continuation practice. Until that bias is rectified, the proposed rules regarding continuation practice will work unfairly against applicants.

Continuations, particularly RCEs, would become rare if first actions were thorough, complete, and well articulated (even if not well reasoned) and if examiners were not highly motivated to make final rejections, even when – as is most often the case – the real reason for the new grounds of rejection is a failure of the examiner to perform a satisfactory first action rather than amendments by the applicant.

In light of these concerns, we make the following suggestions.

- Eliminate the practice of making a rejection on new grounds in a second or subsequent office action final under any circumstances, such that an applicant is always provided at least one opportunity, as of right, to respond to a new ground of rejection. The practice of presenting new art on a second action that is “necessitated by the applicant’s claim amendments” is routine and abusive. Oftentimes, no claim amendments whatsoever result in finalizing a second action. As a result, an RCE must be filed almost without regard to whether the examiner properly deemed the second action final.
- Under the proposed rules, petitions to file a second or subsequent continuing application should always be granted if the last final rejection was premised on new grounds. At town hall meetings, the PTO has indicated that one basis for granting a petition will be that the final rejection was premised on new grounds that could not have been anticipated. We respectfully submit that there should be no inquiry into whether a new ground of rejection could have been anticipated. Besides being an extremely vague standard, this would continue to countenance abusive ground-switching by examiners and would continue to foster the institutional bias in favor of incomplete initial examination.

- Serious consideration should be given to reforming the count system. For example, it may be appropriate to give more credit to an examiner for the first action and correspondingly less credit for a disposal. Along with this, measures to better ensure the thoroughness and clarity of first actions might be pursued. Along the same lines, less credit should be given to an examiner for examination of continuing applications, to more closely align the credit with the lesser degree of effort required to examine what is essentially the same application again. Further refinements of the count system may also be in order, such as measuring examiner credit on a finer level than the application level, so that the credit is somehow commensurate with the actual work involved, such as the number of claims examined, the number of pages in the specification, the number of references submitted in an IDS, the scope of the prior art search, etc. In principle, the system should motivate examiners to give due attention to all claims, to read specifications completely and critically, to give due consideration to all references cited by the applicant, and to search all pertinent classes/subclasses and databases for prior art – the first time. Simply assuming that examiners will do the kind of quality examination they are supposed to do when the system provides them with incentives to do differently is not a valid assumption. Reforming the count system would both enhance patent quality and result in more efficient examination. Finally, it is important that any internal changes to the PTO operations be transparent to the patent bar and applicant community, so that the public can continue to have a high confidence in the vitality of our patent system.
- The PTO should consider its previous proposal to allow applicants to voluntarily defer examination of applications. Deferred examination allows applicants to consider their invention's feasibility, commercial success, and validity based on identified prior art before continuing to prosecute their applications. Deferred examination would be particularly effective in lessening the PTO's increasing continuation application load because it would allow applicants to preserve their filing date without the need to continue examination and prosecution. Many high volume foreign entities, like the European Patent Office, currently allow deferred examination.

3. Limiting the number of continuation applications will move the backlog to appeal

The proposed rule changes will merely shift the backlog of applications from the examination branch to the appeal branch of the PTO. Because first action examinations are frequently poor and second final actions presenting new art are routine, limiting continuations applications to a single application of right, will force applicants to appeal a final rejection rather than to file a continuation application or RCE to respond to the second final action. Although this practice may be efficient in view of the recently instituted pre-appeal conference procedures, this process is unfamiliar to the vast majority of applicants and their agents. Thus, many applicants will fail to avail themselves of the pre-appeal conference procedure, incurring the expense and delay of a full Appeal brief and transferring the backlog of applications to the Appeal branch. Moving backlog from one process to another will neither improve issued patent quality nor make the PTO more efficient and effective.

4. Requiring filing of all divisional applications during the pendency of a first filed application will prevent individual inventors and other small entities from seeking examination of all aspects of their invention

Requiring that all divisional applications be filed during pendency of the parent application, adversely affects individual inventors, academic and non-profit institutions and small companies with limited budgets. Because the proposed rule changes eliminate the possibility of sequential filing of divisional applications, filing fees become due at the same time for all divisional (and any continuation) applications. Under the current rules, individual inventors and small companies have the option of serializing continuation applications allowing them more time in which to pay filing and prosecution fees, and providing a longer time to develop relationships with partners or financial backers to commercialize the technology and evaluate the desirability of filing one or more divisional applications. Large companies likewise delay filing less important divisional applications.

Requiring substantially simultaneous filing of all of the divisional applications from an application will increase the burden on the PTO in some instances, and foreclose the possibility of pursuing patent protection in others. Applicants with ample resources are likely to file substantially more divisional applications to preserve the opportunity to fully pursue subject matter, which would have otherwise been delayed and maybe never filed based on business and strategic decisions. In such cases, the burden on the PTO will increase.

In contrast, individual applicants, academic institutions, small entities and other applicants faced with limited budgets will be unable to pursue subject matter due to the inability to spread costs over time. In the absence of patent protection, many technologies that require substantial investments in development and satisfaction of regulatory requirements prior to commercialization will not make it to the marketplace. This effect is likely to be particularly pronounced in the biotechnology and pharmaceutical arts, where initial discoveries leading to medical applications are made by academic, governmental and other not-for-profit institutions that rely on licensing partnerships to commercialize their inventions. Such institutions typically operate on limited budgets and rely on serial prosecution of inventions supported by a single disclosure as licensing interest and revenue permits. By forcing such applicants to file all divisional applications during the pendency of a single first filed application, prior to establishment of a commercial product, the valuable applications of many discoveries in these sectors will not be the subject of patent application. Consequently, without patent protection, commercial enterprises will be unwilling to partner for the commercialization of such unpatented technologies, and the products and services will not reach the market.

The harm to applicants is not balanced by any commensurate benefit to the PTO or society. Because divisional applications reflect subject matter claimed in the originally filed application, there is no risk that permitting serialization of divisional applications will promote the patenting of subsequently developed technology not originally described or viewed by the applicant as his invention. Similarly, because any delay in issuance due to serialization is offset by a corresponding reduction in term, the cost of delay is borne

solely by the applicant, serving to promote the early filing of divisional applications wherever feasible.

In addition, recent developments in restriction practice, particularly in the biotechnology arts, have resulted in multi-way restrictions of single independent claims into a large and in some instances “an indeterminate number” of inventions. The PTO has recently restricted the search criteria of any invention making use of nucleic acids and/or proteins to a single exemplary sequence. Even when the invention is generic and applicable to a large number of individual sequences, the Office has recently made a practice of restricting search in an application to a single such sequence or embodiment. For a simple example, in the case of a new vaccine vector that can be used to present antigens from essentially any animal or human pathogen, a restriction requirement is typically issued that requires election of a single antigen of a single pathogen on the grounds that each possible antigen of each possible pathogen is a different invention. In such a case, it is not even hypothetically possible for an applicant to achieve examination of the full scope of his or her claims. In the first instance, it is simply impossible to singly and individually pursue each embodiment, and secondly even if one could practically determine the number of individual inventions, the costs of filing such divisional applications would be prohibitive. While such a restriction requirement should typically be predicated on the recognition of at least one generic or linking claim, frequently examiners fail to properly utilize linking claim procedure. Even when a linking claim is formally recognized, it is not uncommon for substantive examination on the merits to be nonetheless restricted to the single elected embodiment. Without a doubt, the underlying problem lies with the intent of the Office to limit search in any generic invention that may involve a nucleotide or protein sequence to a single embodiment searchable exclusively by a single sequence. The proposed rule changes exacerbate the underlying problem with this aspect of examination practice, and are both logically and practically inconsistent with current restriction practice.