From:
Sent: Friday, August 13, 2010 1:06 PM
To: Restriction_Comments
Cc: Stoll, Robert; Focarino, Margaret (Peggy); Therkorn, Linda; Todd Dickinson; Vincent Garlock; Meghan Donohoe; James Crowne
Subject: AIPLA Comments on Restriction Practice, 75FR33584

Attached please find a letter from Alan J. Kasper, President of the American Intellectual Property Law Association (AIPLA), containing AIPLA's Response to Federal Register Notice 75 FR 33584, Requesting Comments on Proposed
Changes to Restriction Practice in Patent Applications.

Many thanks,

Al Tramposch

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AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

August 13, 2010

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Response to Notice Requesting Comments on Proposed Changes to Restriction Practice in Patent Applications
75 Federal Register 33584 (June 14, 2010)

Dear Under Secretary Kappos:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments on the Notice Requesting Comments on Proposed Changes to Restriction Practice in Patent Applications ("Notice"). We believe that restriction practice is an important and timely topic, one that requires prompt attention by U.S. Patent and Trademark Office (USPTO) management.

AIPLA is a national bar association whose more than 15,000 members are primarily lawyers and other patent practitioners in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Its members represent both owners and users of intellectual property.

I. Introduction and General Remarks

The USPTO has properly recognized that restriction practice is a significant area of concern for the USPTO, applicants and the public. AIPLA appreciates that USPTO workload management tools, such as restriction practice, are useful for managing the resources that must be devoted to the examination of patent applications. However, unnecessary or improper restriction requirements are wasteful and costly, directing scarce USPTO resources away from the fundamental purpose and focus of the examination process of determining the patentability of a claimed invention.

Improper restriction requirements also add significantly to the cost and workload of users, and in light of limited resources, may deny applicants an opportunity to obtain the full scope of protection of an invention to which they are entitled. In the view of many practitioners, restriction practice is out of control, and lacking in consistency, conformance to published guidance in the Manual of Patent Examining Procedure (MPEP) and appropriate management oversight. AIPLA appreciates the opportunity to provide comments on restriction practice in general, and on the specific aspects identified by the USPTO for comments.

As a general matter, the concerns with existing restriction requirements are not limited to instances of abuse or mismanagement, but go to the fundamental principles that underlie restriction practice in light of the current economic, technological and global IP environment.

A brief historical perspective may demonstrate the on-going dissatisfaction of practitioners with restriction policies, despite multiple attempts to improve the system. For example, surveys were conducted by the USPTO in the mid-1980s to assess and improve compliance of restriction requirements made under 35 U.S.C. § 121 in response to concerns expressed by practitioners, patent bar associations and industry groups. Efforts made to clarify restriction practice, by improving training materials and guidance in the MPEP and providing closer supervisory review, resulted in a number of significant improvements in the uniformity of restriction practice. Results of these surveys were reported in notices published in the Official Gazette. See Restriction Policy and Practice, 1046 OG 2 (August 1, 1984); Restriction Practice Survey II, 1053 OG 5 (1985).

Another significant example of interaction between the USPTO and the public on restriction practice was the USPTO's "Request for Comments on the Study of Changes Needed to Implement a Unity of Invention Standard in the United States," 68 Fed. Reg. 27536 (May 20, 2003). The USPTO specifically requested comments on many aspects of patent practice and procedure in other major examining offices (e.g., the European Patent Office – EPO) that appear to have a successful unity of invention practice.

Based on an existing resolution in support of a unity of invention standard, AIPLA filed comments on July 31, 2003 (copy attached) that welcomed a comprehensive study of the possible implementation of a unity of invention standard for all United States patent applications, but acknowledged that such a change, should it be adopted, would be a complex and difficult undertaking. AIPLA stated, "It is hoped that the USPTO's study will substantiate the feasibility of implementing a unity of invention standard, and will lead to the realization of substantial benefits by changing existing restriction practices to permit applicants to obtain examination of related claims in a single application."

Similarly, in testimony given before the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property on April 3, 2003, then Executive Director of AIPLA Michael K. Kirk stated, "A change to a unity of invention standard such as that followed under the Patent Cooperation Treaty (PCT) would significantly improve and simplify the examination process," and encouraged a study along an "aggressive timeline."

In later years, AIPLA joined with its colleagues in the Industry Trilateral to recommend to the Trilateral Offices a commonality of application processes and procedures that included the adoption of a PCT-type unity of invention practice.

AIPLA's support for the unity of invention standard is driven by several factors, including its members' dissatisfaction with restriction practice and the apparent success with which other offices and even the USPTO have adopted a PCT- or similar-type unity of invention standard at least for national stage applications. Of even greater currency is the ability of a PCT-type unity standard to support work sharing initiatives, leading to reduced costs, lower pendency, and smaller backlogs, and to provide consistency and compatibility with harmonization initiatives. These provide a compelling incentive to adopt a new national standard. As stated in AIPLA's letter of 2003, the unity of invention standard could benefit applicants, by not having to pursue related claims across a number of distinct applications, the USPTO, through reduced administrative and logistical problems of handling multiple applications with related claims, and the public, from the timelier grant of patents as well as facing fewer patents with related claims.

Since many of the problems associated with improper restriction practice can be traced to the lack of comprehensive guidance, effective supervision, and Examiner accountability, regardless of the standard pursued by the USPTO and the timing for any change, the present request for comments will be useful regardless of which standard is selected. To this end, AIPLA applauds the efforts of the USPTO in seeking comments on what the practice should be before proposing any statutory, regulatory, or practice changes to restriction practice that may affect all applications and the ability of the USPTO to provide a quality examination in a timely manner. If the USPTO decides to propose any changes to restriction practice, AIPLA encourages the USPTO to consider and publish at the same time the anticipated consequences of those changes on all applicants.

AIPLA is pleased to offer the following comments on issues identified in the Notice.

II. Response to Specific Questions

1. What should be included in an Office action that sets forth a restriction requirement?

Under current practice, two criteria must be met to support a restriction requirement, namely, (1) the inventions must be independent or distinct (notwithstanding the statutory language in 35 U.S.C. § 121 that states: "independent and distinct"), and (2) there must be a serious burden on the Examiner if restriction is not required. MPEP § 803. The USPTO is considering the advisability of clarifying the burden requirement to include two situations. The first situation is where the prior art applicable to one invention would "not likely be applicable to another invention" (e.g., because of a different field of art or different effective filing date). The second is one that would encompass both search burden (as at present) and/or examination burden.

AIPLA agrees with the efforts to clarify the meaning of "serious burden" for both USPTO staff and practitioners. In the experience of many practitioners, it does not seem to require much, if any, additional effort for some Examiners to conclude that there is a "serious burden." Arguably any additional work is a burden, but how much additional work constitutes a "serious" burden?

As to the first possible change identified by the USPTO, namely that a "serious burden" exists when the prior art applicable to one invention would not likely be applicable to another invention, we believe that the proposed test is unclear and speculative. "Not likely to be applicable" does not offer any clarity or certainty to the test, and is likely to be interpreted in a wide variety of ways by an examining corps of about 7,000 individuals, to say nothing of 30,000 practitioners. In addition, what is intended by the term "applicable"? Would the prior art have to contribute to a conclusion of anticipation or obviousness for both inventions subject to restriction in order to be "applicable"? A narrower definition would be required to solve the problems that exist with respect to the current practice.

As to the second possible change, namely that "serious burden" encompasses both search and examination, AIPLA has acknowledged in its letter of July 2003 (attached, at page 8) that restriction practice should reflect the additional examining resources implicated by both prior art and non-prior art patentability issues. We would thus favor consideration of any legitimate reason that adds additional work to the examination task. However, several practitioners have expressed concern that consideration of non-prior art issues in connection with an evaluation of a restriction-justifying burden may lead to even greater abuse through seeking every means possible to limit the amount of work that must be done on any one application.

While recognizing that there are non-prior art patentability issues (e.g., written description, enablement, utility, clarity of claim language) that can significantly add to the burden of examination in any given application, it is far too easy for an Examiner to simply allege that such an issue exists in order to establish a "serious" burden. AIPLA can support this proposal in principle, but is reluctant to endorse adoption in practice until the USPTO demonstrates a much greater capability to prevent abuse.

The USPTO is also considering revising an "election of species" practice to require Examiners to group together species that are not patentably distinct from each other so that an applicant could either elect a single species or a single grouping of patentably indistinct species. An applicant would not be required to elect a specific species within a grouping of patentably indistinct species. While an interesting proposal, it is not entirely clear how this would differ from current practice under MPEP § 808.01(a), which states that an election of species should not be required if the species claimed are considered clearly unpatentable over each other. Clarification is therefore requested.

It should also be noted that, because election of species should be required prior to a search on the merits, it is probably rare that an Examiner has evidence that compels a conclusion of obviousness among species before conducting a search and analyzing the prior art.

2. What practice changes would result in more effective ways to seek higher level review of restriction requirements?

First, it would be informative to determine the effectiveness of the current mechanisms in relation to higher level review. For example, does the USPTO have statistics on petitions addressing restriction requirements, especially by Technology Center or by Group? Second, the Notice is unclear about which process it is seeking comments on: (1) "improve the traversal or request for reconsideration process," normally considered by the Examiner who made the requirement, and/or (2) "higher-level review of restriction requirements," relating to review by someone at a higher level than the Examiner, typically by way of supervisory review under 37 C.F.R. §§ 1.144 and/or 1.181.

At any level of review, the process would likely be more consistent, accurate, and cost-effective if there were a common and comprehensive understanding of the criteria for requiring restriction. If current guidelines and examples are inadequate to promote the level of uniformity and consistency sought, they should be revised to facilitate that goal. Training and close supervisory review, at least initially, will be essential to reversing the current trend and achieving a desired level of consistency and conformity.

It would be desirable to provide for review of a restriction requirement before the beginning of substantive examination, including search. If this were possible, obviously improper requirements and/or restriction renegades could be addressed before the USPTO invests any resources in substantive examination that may have to be revisited if the requirement is altered on petition. Some practitioners feel that USPTO officials are more reluctant to revise a restriction requirement on petition when an Examiner has already invested time and effort in examining some part of the claimed subject matter, and particularly at an advanced stage of prosecution.

Examining groups, at least where restrictions are prevalent, should be staffed with a restriction specialist or ombudsperson who could be consulted to quickly review restriction requirements for compliance with the adopted practice. It should be made clear that the ombudsperson would not be consulted until the Examiner had been contacted, at least by telephone, and given the opportunity to address the perceived problem. However, the USPTO should be capable of addressing any restriction issue timely raised by an applicant before a response to a requirement is due, and at least before substantive examination begins.

The USPTO should also consider reviewing the incentives that performance evaluation criteria provide to the use of restriction requirements as a docket management tool.

3. How could the Office clarify requirements for restriction between related product inventions or related process inventions where the relationship is not specifically provided for in MPEP Chapter 800?

The USPTO is proposing to provide a new section in the MPEP that would address restriction between related product or process inventions not otherwise provided for. AIPLA supports the development of guidance that would clarify restriction practice in all areas where additional guidance is desirable, and looks forward to the opportunity to consult with the USPTO on additional guidance before it is adopted as a policy and practice.

The USPTO is considering a policy that an Examiner should not require restriction among claims of an application that define the same essential characteristics of a single invention (i.e., the claims vary from each other only in breadth and scope). This seems to be one instance involving the question of whether the "serious burden" aspect of restriction practice should take into account a search burden only (which seems to be consistent with the proposed policy), or should take into account both search and non-prior art patentability burdens. AIPLA supports a policy and practice that fairly balances the interests of the USPTO and all applicants in achieving a prompt and reliable examination of claimed inventions.

4. How could the Office modify Markush practice?

The USPTO could modify Markush practice in a variety of ways, but the challenge (as noted by the USPTO) is to balance the interests of the USPTO, applicants, and the public in the context of current statutory, regulatory, and judicial frameworks. Examiners need to be aware of and understand applicable judicial guidance in decisions such as *In re Weber*, 580 F.2d 455 (CCPA 1978), *In re Haas*, 580 F.3d 461 (CCPA 1978), and *In re Harnisch*, 631 F.2d 716 (CCPA 1980).

The USPTO states that it is considering whether to revise Markush practice in a variety of ways. The first suggestion addresses a situation where an elected species is determined to be patentable, and the Examiner would expand the examination to the extent necessary to determine the patentability of a claim containing the elected species (i.e., any nonelected species within the scope of the claim). Once determining that the claim (it is unclear whether this would cover any claim containing the elected species, or just the broadest claim) is unpatentable as to any nonelected species for any reason, search and examination would not be extended to cover all nonelected species. It is not clear how this proposal differs from the published policy of the USPTO reflected in MPEP § 803.02 that is expected to be followed in the circumstances described. Clarification is requested.

The second suggested revision is to clarify the circumstances under which an Office action may be made final when a claim containing a Markush group is amended to delete a member of the Markush group that is arguably unpatentable. Again, this proposed revision appears to align with current practice as expressed in MPEP § 803.02 that expressly references the guiding principles in MPEP § 706.07(a) that are contained in the proposed revision. Clarification of the proposed change is again requested.

5. How could the Office improve rejoinder practice?

In general, Examiners appear reluctant to follow rejoinder practice, as it may require additional work—particularly in the form of compliance with §§ 101 and 112 issues—after completing examination of the elected invention. The USPTO is considering whether to define "rejoinder" as the practice of withdrawing a restriction requirement where (1) all claims to the elected invention are allowable, and (2) it is readily apparent that all claims to a nonelected invention are allowable for the same reasons that the elected claims are allowable. Again, this would be consistent with current practice that appears to permit rejoinder where these factors are limited to prior art considerations. If other non-prior art examination issues are considered, the second condition may lead to a different result.

The USPTO goes on to suggest that claims that meet the second condition for rejoinder may include those that (1) properly depend from an allowable elected claim, (2) include all of the limitations of an allowable elected claim, or (3) require no further search and/or examination. Claims that may not be eligible for rejoinder would include those that require additional consideration of the prior art or raise utility, enablement, or written description issues not considered during examination of the allowable elected claims. As AIPLA understands this proposal, claims that meet any one of the three alternative conditions for rejoinder would be eligible for rejoinder unless some additional prior art or non-prior art issue is raised that was not considered during examination of the allowable elected claims.

If AIPLA's understanding is correct, this proposal raises the same concerns stated earlier about the potential for abuse when Examiners can assert that a new non-prior art issue is raised, without any effective procedure to have that determination reviewed in a timely manner. The USPTO also has suggested that it is considering instructing Examiners that they must consider rejoinder issues when the elected claims are found allowable and must reevaluate both aspects of the restriction requirement (i.e., "independent and distinct," and "serious burden") before permitting rejoinder.

AIPLA supports the development of clear and practical criteria for determining whether rejoinder should be permitted. As noted above, AIPLA can agree in principle that a determination of "serious burden" should include both prior art and non-prior art issues that contribute to additional burdens, but AIPLA remains concerned that such an expansion will open the door to abuse that cannot be effectively controlled by the USPTO. A consistent and predictable practice that fairly balances the interests of the USPTO, applicants, and the public will first require the development of a clear and workable definition of "serious burden," along with examples that will aid both USPTO staff and practitioners.

6. What other areas of restriction practice can the Office improve and how?

As stated above, AIPLA has long supported the adoption of a unity of invention standard as the national restriction practice. The USPTO is encouraged to consider a number of factors in crafting a unity of invention standard, including those set out in AIPLA's letter of July 2003 (attached), as well as to provide the following: a description of the actual USPTO implementation of unity of invention practice in PCT national stage applications (how are Examiners implementing the standard? how does the standard used compare to PCT standards?); an outline of the changes necessary to implement unity as a national practice and an objective assessment of the anticipated consequences of such changes; an assessment of costs increase and effects on income stream, and of pendency increase; and an analysis of whether Examiners would be given additional time to conduct examination, and possible effects on examination quality.

On another matter, there are some concerns about the fees paid for claims that are not examined because they are not elected pursuant to a restriction requirement. While it is recognized that fees are paid for filing claims, as opposed to examining claims, the fees are expected to compensate the USPTO for the cost of examination, not filing. AIPLA suggests that a mechanism should be found or created for authorizing a refund of any excess claims fees paid for claims that are not examined due to a restriction requirement.

AIPLA appreciates the opportunity to provide these comments on the Notice, and would be pleased to answer any questions that these comments may raise. We look forward to participation in the continuing development of rules applicable to USPTO patent practice.

Respectfully submitted,

Alan J. Kasper
President

Attachment

AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
2001 JEFFERSON DAVIS HIGHWAY ▪ SUITE 203 ▪ ARLINGTON, Virginia 22202

Mr. Nicholas P. Godici
Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

July 31, 2003

Re: Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in The United States
68 Fed. Reg. 27536

Dear Commissioner Godici:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments on the possible implementation of a unity of invention standard in the United States and the specific issues identified in the subject request. The enclosed remarks reflect an amalgamation of the many and diverse views among members, the views of the Association on the topics raised by the request for comments.

AIPLA is a national bar association whose more than 14,000 members are primarily lawyers in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

I. Introduction and General Remarks

AIPLA welcomes the comprehensive study of the possible implementation of a unity of invention standard for all United States patent applications. It is hoped that the USPTO's study will substantiate the feasibility of implementing a unity of invention standard, and will lead to the realization of substantial benefits by changing existing restriction practices to permit applicants to obtain examination of related claims in a single application. Applicants could benefit by not having to pursue related claims across a number of distinct applications. The United States Patent and Trademark Office (USPTO) will also likely benefit from reduced administrative and logistical problems of handling multiple applications with related claims. The public could also benefit from the timelier grant of patents, as well as facing fewer patents with related claims.

Under unity of invention, it is likely that a greater percentage of U.S. patents would issue with all the claims deemed necessary by the applicant for effective protection included in a single patent. The natural consequence of this would be fewer applications pending before the

USPTO, and fewer patents with claims related to the same general inventive concept. The USPTO, in particular, would hopefully reduce its administrative overhead due to the need to process fewer patent applications. The USPTO would also hopefully be able to adopt more efficient examination procedures and significantly reduce its operational costs associated with managing, docketing, tracking, publishing and storing patent application records.

Many patent applicants, when faced with a restriction requirement, elect and pursue examination of one set of claims, but ultimately do not pursue all non-elected claims. Most applicants defer the decision on filing divisional applications until prosecution on the merits regarding the elected category is closed. When prosecution of the elected category is at least somewhat favorable, many applicants view the marginal benefit of pursuing divisional applications as not justifying the costs and thus decline to file such divisional applications. For a variety of reasons they may ultimately regret such a decision. For example, when the patent is enforced, a court may find no infringement of an apparatus claim in circumstances where method claims closely linked to the apparatus would have been found to have been infringed.

Many applicants may pursue divisional applications out of commercial necessity. This creates many undesirable consequences. It increases costs for the applicant, not merely in terms of official fees but also in terms of the attorney fees involved in preparing, filing and prosecuting the additional application. It creates unnecessary uncertainty and costs for third parties. For example, the first elected or primary patent, the divisional patent(s) and their pre-grant publications are essentially redundant prior art, which unnecessarily complicates patent searches. In the litigation or opinion context, the review of the additional file histories involved will pose unjustified additional costs. The seriatim prosecution of divisional applications makes it likely that the subsequent applications will not be examined by the original examiner, which often creates inconsistent patentability results and conflicting file histories that reflect substantially different positions taken by the various examiners. These factors seriously complicate litigation – leading to increased costs and uncertainty – for both the patentee and accused infringer. Frequently, the examination of the divisional application occurs months or even years after the first family member was examined. This reduces efficiency and creates anomalous patentability results.

The focus of the request for comments is the potential adoption by the USPTO of the “unity of invention” practice followed under the Patent Cooperation Treaty and by the EPO. This will be a complex and difficult undertaking, requiring legislative and regulatory changes, along with significant operational changes. This is reflected in the answers provided below that respond to the specific questions presented in the request for comments. Accordingly, AIPLA supports the decision of the USPTO to conduct a comprehensive study of the changes needed to address the concerns raised by the current restriction practice, including the consideration of various aspects of the PCT and EPO-style unity of invention practice.

AIPLA appreciates that workload management tools, such as restriction practice, are useful to manage the resources that must be devoted to the examination of patent applications. Improper or otherwise unnecessary restriction requirements are unduly wasteful and costly for applicants and the USPTO and divert scarce resources away from the fundamental purpose and focus of the examination process of determining patentability of a claimed invention. Whatever system is adopted to manage the workload of the Office, AIPLA believes that examiner training, supervision, and accountability are essential.

As part of the unity of invention study, AIPLA also urges the USPTO to survey the current practices of examiners in applying the "independent and distinct" standard articulated in 35 U.S.C. §121. Many AIPLA members believe that the statutory standard is being misapplied in many groups. The concerns are most pronounced within the biotechnology and chemical groups, but are voiced in virtually all technology sectors. Thus, while AIPLA supports a study of substantive reforms current standards and practices, there is a substantial need for the USPTO to assert more control and accountability over use of its current restriction authority.

II. Responses to Specific Questions Raised

Issue 1(a): Should the USPTO study ways to adopt EPO claim treatment practice, including normally allowing only one independent claim per category of invention, when considering ways to adopt a Unity of Invention standard, and why?

No. AIPLA opposes the adoption of practices in the USPTO that would limit the ability of an applicant to present more than one independent claim in each statutory category, as is presently the case in European style claim practice. The treatment of claims under U.S. law, both during examination and after issue, is based on a fundamentally different approach than that of European law and practice (i.e., the use of a peripheral claiming theory in the U.S., contrasted with the central claiming theory in Europe). It would be inappropriate and unworkable for the USPTO to adopt procedural rules for examination based on a European approach to claim interpretation.

Allowing only one independent claim per category of invention (e.g., apparatus, composition, method of making, method of using, etc.) fails to taken into account important differences in the law with respect to claim interpretation and the scope of claim coverage, that are peculiar to U.S. law as developed by the Federal Circuit. For example, literal interpretation of functional vs. non-functional claims, and claim coverage under the doctrine of equivalents of functional vs. non-functional claims are good examples of reasons why more than one independent claim in any one category of invention should not be limited to a single independent claim. Applicants should thus continue to have the flexibility to define their inventions in each category of invention by resort to claims of differing type (e.g., functional vs. non-functional claims) as well as differing scope (e.g., broad, intermediate, narrow).

Moreover, Applicants are often frustrated by the requirement in the EPO that additional elements of an invention must be claimed, if at all, in a separate application unless the applicant is willing to include these elements in dependent claims. This increases cost needlessly, and often results in an Applicant's sacrificing claim coverage that might otherwise be granted for different combinations that are worthy of protection under independent claims. A single invention can encompass a number of separate elements that lend novelty to a combination claim. Where these elements are independently significant, additional applications have to be filed in the EPO to protect fully the invention.

Notwithstanding the above, however, AIPLA believes that consideration should be given to adopting the multiple dependent claim practice permitted in Europe, which would result in at least helping to reduce the number of independent claims otherwise presented in an application.

In summary, AIPLA believes that an applicant should retain the freedom to present a reasonable number of independent claims of differing type and varying scope as deemed necessary to ensure effective protection for an invention, taking into account the possibilities of the various circumstances of infringement that will be encountered in the market (e.g., induced and contributory infringement).

- Advantages of Permitting Multiple Independent Claims in Each Category

Under established U.S. practice, there are many reasons for having more than one independent claim in each category of invention. For example, one factor, unique to U.S. practice, that mitigates in favor of having claims of differing scope for each category of invention is the doctrine of file history estoppel. In other words, claims of differing scope will tend to maximize the chances that at least one claim will be allowed by any given examiner at the USPTO with out estoppel by amendment or argument having been created, thus preserving resort to the doctrine of equivalents for such claim and thereby increasing the likelihood that the claim may be found to be valid and infringed by any given court.

Other factors are technology specific. Applicants should be able to present claims that directly cover a use of the invention, without reliance on induced or contributory infringement. Applicants should also be able to present claims that address contingencies of interpretation both within the USPTO and by courts.

Yet other factors include the case where an inventive system may also include a separately inventive component. In that case, it may be advantageous to have separate independent claims to the system and to the component. There may be certain situations in which prior art considerations require the component independent claim to have more elements than the portion of the system independent claim that relates to such component. This may be the case where such elements are necessary to avoid anticipation by a non analogous reference. The non analogous nature of the reference may render it inapplicable to an obviousness rejection of system independent claims while nevertheless leaving it as an anticipatory reference to a broader version of the component independent claim. Some of these situations arise due to aspects of U.S. examination practice that might cause claim elements to not be given particular weight. For example, some elements might be regarded as indefinite or as mere statements of intended use. Anecdotal experience with European examination indicates that such considerations are not as significant in the EPO.

- Different Claims of Generally Similar Scope

In the mechanical, electrical, and software fields, a statutorily based factor for claim drafting is 35 U.S.C. 112(6). For an apparatus invention, it is generally regarded as good practice to include pairs of complementary independent claims of similar general scope: one independent claim with purely structural limitations falling outside of §112(6); and another claim with one or more elements written in functional language subject to §112(6).

Expanding upon this reasoning, in any given case there may be reasons to have additional independent apparatus claims of generally similar scope but with different combinations of functionally written elements. It may be desirable to use alternate generic terms for claim elements even within entirely structural claims. Considerations of prosecution history estoppel may mitigate in favor of having numerous independent claims of the same category.

- Operating Conditions of Apparatus Inventions

Especially with mechanical inventions, there may be reasons to have independent claims to the apparatus in different conditions. For example, a machine might be claimed in different stages of operation. As with the system/component situation, a claim to an apparatus in a given condition of operation may well need fewer specific elements relating to parts of the apparatus than does a "first element connected to a second element" type of claim that does not reference the operation of the apparatus.

- Different Points of View or Manner of Using Software Implemented Inventions

Software and business method inventions may call for claims which are designed to protect the software by taking into account where the software is used (e.g., by a server as opposed to a client computer – e.g. protecting the software from these different "points of view" so to speak), as well as protecting the software based on how it may be used by different users (e.g., purchaser or consumer, seller, or website operator – again different "points of view" in regard to how the software invention may be used and claimed).

- Chemical and Biotechnology Inventions

Similarly, in the chemical and biotechnology fields, inventors may need protection for various embodiments of an invention. For example, a new gene may give rise to a number of different embodiments that will be specifically claimed. The nucleic acid encoding the gene gives rights over a key element enabling production of the protein that may be the active ingredient of a new drug. The expression production (i.e., the protein) encoded by the gene is the active ingredient. Cell lines that have been transformed to express the nucleic acid are the commercially important environment in which the protein is made. Individual therapeutic methods based on the identified therapeutic role of the expression product must be claimed to ensure protection for the commercial use of the invention. Downstream inventions, such as antibodies that bind to the protein and modulate particular activities that present additional commercial opportunities also are related to the sequence and its expression product.

Certainly, some of these embodiments will raise distinct issues of patentability relative to those raised for the nucleic acid, per se. However, the additional effort required of the USPTO to examine these downstream inventions frequently does not justify the burden on the applicant of filing separate applications. Retaining the option of keeping related claims to various aspects of these inventions together, including by payment of additional fees and provision of additional examining time credit for an examiner, could yield substantial benefits.

A comparable situation exists in the chemical arts, particularly for bioactive substances. Typically, a class of molecules is identified that share a desired activity. Slight variations in the chemical structure of the common structure shared by the class often will not have a significant effect on the activity. The activity in question gives rise to a utility for the invention – either a therapeutic, diagnostic or related method – that is integrally related to the utility of the compound. An examination of the class typically will raise and address many of the patentability issues that would govern patentability of the method claims. Potential efficiencies can thus be realized by allowing examination of claims to related members of the class, along with claims to methods that are linked to the utility of the class, in a single application.

Issue 1(b) Should the USPTO emphasize the examination of independent claims and modifying the examination of dependent claims in the same fashion as the EPO? If so, would there be any reason to consider changes to the presumption of validity under 35 U.S.C. 282 of those dependent claims?

No, the USPTO should not modify its practices concerning the examination of dependent claims.

A full examination of each dependent claim serves important public policy objectives, and improves the quality of each patent grant. Dependent claims also differentiate an associated independent or base claim in a way that provides extremely useful insights into patentability and enforcement issues. For example, in explaining the rejection of a dependent claim, an examiner often will provide the applicant with useful insights into the grounds for rejection imposed on an independent claim. Many applicants rely on the examiner's indication of allowable subject matter made through a suggestion to incorporate limitations in a dependent claim into an independent claim. Capturing this interchange in the prosecution history of the patent also provides insight to the public and to courts as to the scope of the claims allowed by the USPTO. Even when the USPTO finds an independent claim free of the prior art, opinions expressed by an examiner regarding the form, scope and support for a dependent claim help applicants make more informed decisions about which dependent claims are necessary to provide the most effective protection.

In view of the foregoing, the statutory presumption of validity should not be altered. Any changes regarding the presumption of validity must consider both the statute and the judicial implementation of that statute.

Issue 2(a): If the USPTO adopts a unity of invention standard, should the USPTO provide applicants the option of a PCT-style unity of invention practice to pay for additional inventions for lack of unity of invention in the same application?

Yes. Within reasonable limits, the USPTO should allow applicants to pay additional fees to obtain examination of claims that the USPTO believes will raise additional prior art and/or patentability considerations implicating substantial additional work by the USPTO. The fees (and the time-credit provided to examiners) should reflect the additional amount of resources that the USPTO will need to expend to ensure a comprehensive examination of the additional claims. If the applicant does not wish to pay the additional fees in the application being examined, he or she should retain the right to file a divisional application directed to the claims for which additional fees are being required.

Reforming restriction practice to give applicants the discretion to pay additional fees to obtain examination of all related claims in a single application will help reduce transactional and administrative costs to applicants and the USPTO. Such a change would also permit a reconciliation of the invention-focused orientation of the USPTO with the product–focused orientation of many businesses. It is the nature of many technologies and markets that a given new product introduced by a business will incorporate multiple different inventions lacking unity. For example, a new software product may incorporate one group of inventions relating to how data is handled and another group of inventions relating to the user interface. A new industrial machine may have several distinct inventions relating to how a workpiece is handled and several others relating to the work performed on that workpiece or to the workpiece itself. Under existing U.S. restriction practice, an initial application may be filed with claims to all these inventions. These claims, being distinct and lacking unity will be subject to restriction.

There may be advantages to permitting the examination of these claims in a single application and their issuance in a single patent, but such a practice could also introduce administrative complexities and questions of fairness to other applicants that would be disadvantageous.

The additional fees should reflect the additional costs of examination. As discussed below, present excess claims fees could substantially satisfy the additional costs of examination. If a further fee is charged, there should be an offset against excess claim fees.

Issue 2(b): If so, should the USPTO consider any changes to patent term adjustment under 35 U.S.C. 154(b) for applications which have more inventions examined in a single application under a Unity of Invention standard than are permitted under current practice? In view of the fact that examining multiple inventions in a single application could cause examination delay in other applications, what other revisions to patent term adjustment provisions under 35 U.S.C. 154(b) should be considered by the USPTO, or should the USPTO also consider revising the order that cases are taken up for examination?

The USPTO should defer any effort to revise the statutory authority governing patent term adjustment until it is demonstrated that adoption of any new standard or practice actually results in significant delays in examination of applications. The answer to the USPTO's inability to cope with the workload, whether as a result of some more complex applications or as a result of more applications filed due to restriction requirements, is not to simply give itself more time to complete its work through term extension. Rather, the USPTO should continue to work on improving its core examination competency as it is presently committed to doing under its 21st Century Strategic Plan in order to solve any of the suggested difficulties and to achieve its stated objective of an average 18-month pendency in every technological field.

Moreover, as noted above, reducing the total number of applications that will require examination may yield an overall increase in productivity by the USPTO. For example, the increased examining and operational resources made available as a result of a smaller population of pending applications requiring examination can be applied to reduce overall pendency.

AIPLA is not in favor of adding further complexities to the patent term adjustment provisions and does not favor consideration of revising the order of examination.

Issue 3(a): Should the USPTO adopt, for national applications, the practice currently used under the PCT of examining the first claimed invention where there is a holding of lack of unity of invention? Optionally, where unity of invention is lacking: (1) should the USPTO examine the first claimed product or the first claimed invention if there are no product claims; or (2) should applicant be given the opportunity to elect an invention to be examined?

No, the USPTO should not adopt the PCT practice of examining the first claimed invention where there is a finding of lack of unity. Applicants should always be given the opportunity to elect which invention is to be examined first. An applicant's priorities may change over time or they may become aware of prior art that may make the patentability of a particular invention more problematic. In addition, by giving applicants an opportunity to elect from

among a plurality of inventions identified by the examiner, applicants at least have an opportunity to persuade the examiner of the impropriety of the requirement or seek immediate supervisory review before any search and examination time is wasted. It makes little sense for the USPTO to waste scarce examining resources on the search and examination of an invention in which applicants are no longer interested in patent protection. Retaining the practice of a first contact between the USPTO and an applicant where a finding of lack of unity is made will give applicants the opportunity to traverse a holding of lack of unity, to amend the claims to establish unity, or pay additional fees to have claims lacking unity examined (if that option is made available).

Issue 4(a) When adopting the unity of invention standard, should the USPTO follow the practice of performing only a "partial search" if the examination of the entire scope of the claims is unduly burdensome due to non-prior art issues?

AIPLA opposes adoption by the USPTO of a practice of conducting a "partial" search of an application. The experience of AIPLA members is that a reasonable search burden is encountered in the overwhelming majority of cases. Indeed, it is acknowledged that the USPTO does not and cannot do as exhaustive a search of the prior art as a defendant may be inspired to do by litigation. Instead, the USPTO performs searches that are reasonably related to the scope of the subject matter claimed. Provided that additional fees will be paid where additional claims implicate a broader search obligation, AIPLA sees no justification for conducting a partial search of an application.

Restriction practices should reflect the additional examining resources implicated by both prior art and non-prior art patentability issues. Thus, restriction practice should not be based exclusively on the search burden implicated by claims that share or do not share a common technical feature relative to the prior art. In many settings and technology areas, significant issues of patentability requiring substantial examining resources concern issues that are not related to the prior art. Thus, for example, a compound and its use in treatment of a disease may not raise distinct issues of novelty or nonobviousness determinations, and may not thereby implicate different searches, but frequently do present distinct issues of patentability with respect to 35 U.S.C. 101 and 112.

Issue 4(b): Alternatively, should the USPTO assess adequacy of the disclosure and industrial applicability in addition to the prior art when determining whether the claims' common feature makes a contribution over the prior art?

The USPTO should address adequacy of disclosure and utility as part of its determination of the workload implications associated with an application. The assessment should be made directly, not through the implications of the distinct issues for prior art searching or evaluation. Thus, the USPTO should consider the implications of the claims presented for creating additional examining burdens in evaluating compliance with the requirements of 35 U.S.C. 101 and 112, in addition to the implications for conducting a search. Those considerations may justify the imposition of additional fees to permit examination of such claims in a single application. Such

additional fees should be lower than those associated with claims that require additional and distinct prior art searches.

Issue 5: Which of the following approaches should the USPTO propose in regard to any fee increases: (1) all filing fees; (2) all filing fees and an additional fee for examination of claims that lack unity of invention with an elected invention; (3) increased issue and/or maintenance fees of all applications; (4) increased issue and/or maintenance fees for applications paying the additional invention fee; or (5) a combination of two or more of (1)-(4) above.

As an initial matter, AIPLA believes that it is reasonable to charge increased fees for additional work that may be required. Thus, charging additional claim fees at the time of filing, as well as charging an additional fee for examination of claims that lack unity of invention do not seem unreasonable, if those fees are rationally related to anticipated increases in work required by an examiner. However, beyond that, AIPLA does not accept the proposition that adoption of a more liberal unity of invention restriction standard will necessarily create significant revenue shortfalls for the USPTO. AIPLA recognizes that more claims will be examined in each application under a more liberal restriction standard relative to the current restriction standard. The actual impact of such a change, however, may not be as significant as the USPTO has suggested:

- By examining more related claims in a single application, each claim can be examined more efficiently than under current practices.

- Inclusion of more claims per application will also generate more fees per application due to excess claim fees, which the USPTO has not suggested will be eliminated.

- Under a more liberal restriction standard, the total number of applications requiring examination will decrease; leading, in turn, to a decrease in the overall workload of the USPTO. Unless the USPTO substantially decreases the size of its examining corps, it should be able to produce the same relative output of examined claims at a lower cost than under current practices.

- Compared to current practices, fewer patents will issue. While the USPTO will see a decrease in issue and maintenance fee revenue, the size of those decreases may not be significant. For example, by issuing fewer patents, the USPTO will incur fewer costs of publishing patents. The amount of "lost" maintenance fees also is likely to be nominal, given the practice of most applicants of not seeking patents on all claims that are subjected to restriction requirements.

Thus, given the aggregate savings to the USPTO of having to process fewer applications, and the ability to capture excess claim fees to account for the increase work associated with each application, it would be premature to project any level of increased costs to the USPTO stemming from a change to the unity of invention standard.

AIPLA is prepared to address the revenue implications of a unity of invention standard once the USPTO establishes that additional revenue will need to be generated. In the event that fees do need to be adjusted, as noted above, AIPLA believes that the costs of examining additional claims should be borne by those who benefit from the change in practice. Such

additional costs should be collected through a combination of the second and fourth options (i.e., additional fees for additional claims and, if appropriate, adjustments to maintenance fees).

Issue 6 How should work be assigned to ensure that examination quality would not suffer if examiners have to examine multiple inventions from different disciplines in a single application? Should the USPTO consider: (1) using team examination, similar to the EPO where applications are examined using three-person teams called "examination divisions"; (2) extending the use of patentability report procedures provided for in MPEP 705; (3) maintaining the current process of a single examiner on an application; or (4) using some other option of how work is performed by examiners?

In presenting this question, the USPTO suggests that there will be a high incidence of examiners needing to consult with other examiners in order to conduct a comprehensive examination of all presented claims in an application. Experience shows, however, that most examiners are capable of handling examination of all related embodiments of an invention, even where those various embodiments are classified differently, and the classifications are handled by different art units. Indeed, the USPTO has already changed its group and art unit structure in certain technology areas to handle all related aspects of certain types of inventions (e.g., in Group 1600, several art units are organized to handle examination of all aspects of a particular family of proteins). Incentives can be provided to examiners in the form of a Generalist rating where the examiner routinely accepts and seeks opportunities to examine multiple inventions in a single application in a competent manner. Thus, AIPLA believes the frequency with which one examiner will need to reach out to a different examiner for examining expertise will be low.

Notwithstanding the foregoing comment, AIPLA believes that the USPTO should have the authority to determine how best to examine various claims that are kept together in a single application. If the USPTO determines this may be best done through team examination, the USPTO should implement procedures that give all members of the team the necessary examining credit to ensure that each examiner performs the work that is needed to ensure a thorough examination.

AIPLA notes, however, that team approaches to examination could drive up costs and dilute accountability. Thus, use of team examination should be minimized. Other options the USPTO could explore could include use of patentability reports or the sequential transfer of the case to another examiner. The patentability report procedure may be advantageous to the extent that each portion of the Office Action is signed by a specific examiner, making it clear who has negotiating authority and responsibility for each issue. Accordingly, AIPLA encourages the USPTO to experiment with the various approaches that it has identified as a part of its study so that a better decision can be made once the benefits, risk, and problems with each approach have been identified. In general, the approaches of team examination and use of patentability report procedures would clearly contribute to inefficiencies in the examination process, but may be outweighed by demonstrated improvements in the quality of examination.

Issue 7: Should the USPTO use its authority under the continued examination provisions of 35 U.S.C. § 132(b) (authorizes requests for continued examination or RCE practice) to permit applicants to pay an RCE fee and submit or rejoin claims to additional inventions after a prosecution has been closed on a first invention, so long as

the claims presented with the RCE fee either depend from or otherwise include the features of the allowed claims which make a contribution over the prior art? Should this option be available only to applicants whose applications are published? If so, how should the new RCE fee be set relative to the current fee structure?

The USPTO does not need to exercise its authority under 35 U.S.C. § 132(b) to make the option outlined in Issue 7 available to applicants. As presently understood, it appears that the Office is suggesting adding an additional RCE fee be paid to enable rejoinder of claims pursuant to MPEP 821.04. Under the current rejoinder practice, applicants are permitted to rejoin claims to additional inventions after prosecution of a first invention has been completed so long as the claims rejoined either depend from or otherwise include the features of the allowed claims of the examined invention. The USPTO has failed to identify any additional benefits that applicants will enjoy over current rejoinder practice for the privilege of paying yet an additional fee for an existing practice. If the further examination of the rejoined claims on issues other than prior art has added a significant burden to the examination process, that burden should be measured and an additional fee, commensurate with the additional burden, proposed by the USPTO.

Issue 8: Should the USPTO use its authority under continued examination to permit requests that the USPTO continue examination of claims which were withdrawn from consideration? If so, how should the loss in issue and maintenance fee collections be offset relative to the current structure?

As part of its study, AIPLA encourages the USPTO to experiment with the suggested procedure in order to obtain better information on the potential costs and benefits of the procedure. To the extent of that multiple inventions will be searched and examined in a single application, it would appear most beneficial to applicants, the USPTO, and the public if this examination of multiple inventions was conducted concurrently rather than sequentially. There is no necessity to impose a fee in a pilot project to experiment with this procedure as restriction is always discretionary with the USPTO. Regarding the fee implications for the suggested practice, reference is made to our comments on issue 5, namely, that any increased costs of examining additional claims should be borne by those who utilize such procedures.

Issue 9: Should the USPTO consider (1) seeking a change to 35 U.S.C. § 121 to adopt a unity of invention standard (and if so, what would such statutory change be, including whether such a statute would provide for applicants to pay for additional inventions that lack unity of invention to be examined in the same application); (2) maintaining the current restriction practice in the USPTO; and/or (3) modifying the USPTO rules and procedures to adopt aspects of unity of invention practice without making any statutory changes (if so, in what manner should rule changes be made)?

The USPTO is presently engaged in a comprehensive re-evaluation of virtually all aspects of the examination process. Doing so without addressing the issue of restriction practice is short-sighted and will undermine the legitimacy of the effort underway. Because the question

of restriction practice underlies so many variables in the management of the examination process by the USPTO, the issue should be addressed now, and done in a comprehensive manner.

It is clearly premature to consider any statutory change in 35 U.S.C. § 121 to adopt a unity of invention standard, at least until the USPTO clearly describes the practice that it intends to adopt under that standard. Although there are significant differences of opinion about the advisability of adopting a unity of invention standard for national restriction practice, a meaningful debate is not even possible until the USPTO describes the practice it intends to adopt under a unity of invention standard. For example, to the extent that a unity of invention standard would necessarily be accompanied by a restriction on the number of independent claims, an option to provide a second class examination of dependent claims, partial searches, and prohibitive increases in fees, it would not attract any significant support among users of the system. While there may be problems with the present restriction practice, these problems would not be solved by hastily adopting a unity of invention standard that does not take into account the true underlying causes of those problems. In areas of the USPTO that are attracting the most criticism on restriction practice, the USPTO should promptly initiate at least a survey of the restriction practices employed to determine whether the problem is with the restriction standard and guidelines and/or with the implementation and application of that standard and guidelines by the USPTO patent examiners and/or some other contributing factors.

Issue 10: Do you have any other solutions to offer which are not addressed in this notice?

Implementation of any system will be tied to issues of examiner compensation. Implementation should be tailored to minimize chances of gaming of the system by examiners and managers to generate counts or move cases off a docket. This may well require changes to the system so that the examiner time allocated to a given case is decoupled from actions such examiners may take regarding issues relating to restriction.

We appreciate the opportunity to provide comments on the "Request for Comments on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States," and will be happy to assist in any way we can.

Sincerely,

Michael K. Kirk
Executive Director