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July 28, 2003

The Honorable James E. Rogan Under Secretary of Commerce for Intellectual Property And Director of the U.S. Patent and Trademark Office Mail Stop Comments—Patents Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313–1450 ATTN: Robert Clarke

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, May 20, 2003)

Dear Director Rogan:

Intellectual Property Owners Association (IPO) appreciates the opportunity to comment on the Study of the Changes Needed to Implement a Unity of Invention Standard in the United States. IPO endorses the USPTO's recognition of a need to reform restriction practice and to study other systems such as the unity of invention standard employed under the PCT System.

While IPO believes current restriction practice needs to be changed, it is not clear at this time whether the current system should be discarded in favor of another system or whether it would be preferable to address and correct the flaws of our existing system. IPO has supported the unity of invention concept generally in the past, and we continue to believe some form of unity of invention standard offers solutions to problems with the existing system, but we support a comprehensive issue-by-issue study.

Many IPO members view restriction practice as merely a means for the USPTO to raise additional revenues with fees for multiple applications and simplify examination so that disposition of an application can be achieved in a targeted time regardless of complexity. The "real" pendency time of parts of an invention that are shifted into divisional applications is usually overlooked. Even for closely related claimed inventions which would be most efficiently examined together, an Examiner can select from among the myriad of standards set forth in the MPEP to justify a restriction requirement under the current system based on an ever expanding classification system. The remedies to the applicant for improper and undue restriction in the current system are inadequate, as a restriction requirement is reviewable only by petition, not by appeal to the Board. In fact, under current practices applied in some examining groups, applicants may be subject to restrictions applied not only among claims, but even within a single claim based on E.I. DuPont de Nemours & Co.

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searching order chosen by the Examiner (see MPEP 803.04). In such situations, an applicant's statutory right to claim what he regards as his invention may be sacrificed.

IPO believes there may be inherent advantages in certain aspects of a unity of invention system which may at least partially address some of the problems associated with the current restriction practice, foremost of which include (1) the concurrent examination of related inventions that would currently be restricted and examined separately in later divisional applications and (2) the granting of a single patent covering related inventions, instead of several patents which must be separately maintained and which may create serious additional problems where litigation ensues. However, the number and complexity of the questions posed in the Request for Comments, which are primarily directed towards the possible implications of employing a unity of invention standard within the current U.S. patent examination system, demonstrate that adoption of a unity of invention standard must be examined carefully prior to its implementation in any form, along with the consideration of any other possible changes to the current restriction practice.

The USPTO is encouraged to study the adoption of a flexible, equities-balanced examination procedure. One size need not fit all. The search and examination process for a simple mechanical device described by reference to a single drawing should not set the standard for a complex biotechnology application described by reference to multiple DNA sequences. No invention should be subjected to division into pieces small enough simply to be searched and examined in a "standard" time frame. If the PTO is to be funded by user fees, then the fee system should be adjusted to allow for recovery of average actual costs in an examination system that accommodates applications of variable scope.

The following comments are submitted in response to the specific issues raised by the USPTO to assist the USPTO's consideration of whether a unity of invention standard would be appropriate for our patent system.

Issue 1: Unity of Invention as practiced in the EPO is interlinked to EPC-style claim drafting and EPO claim treatment practice, including certain limitations on claiming that are not present in current United States patent practice. For example, the EPO (under EPC rule 29(2)) usually allows only one independent claim per category of invention (category of invention is that of product, process or apparatus of use), and emphasizes the search and examination of independent claims. In contrast, the USPTO searches and examines every claim, independent and dependent, and every limitations of every claim. In addition, EPC-style claim drafting is generally termed "central claiming". In central claiming, the inventive concept is essentially claimed in the independent claim. If the independent claim is found allowable, the EPO examination will not be unduly concerned with respect to the dependent claims, according to EPO Guidelines, C-III, 3.6.

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?

**COMMENT:** NO. Limiting the number of independent claims would be incompatible with the requirements of U.S. substantive law. It is absolutely crucial to the U.S. patent system to allow applicants to present multiple independent claims to a single invention, e.g. without reliance on induced, contributory or equivalents infringement. For example, multiple independent claims can account for technical rules for imports, exports, kits for assembly, products of a patented process, component parts and built-up systems, or repairable components.

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 by any reason to consider changes to the presumption of validity under 35 U.S.C. 282 of those dependent claims?

**COMMENT:** NO. Each claim, whether independent or dependent, must be considered on its own merit with respect to patentability, particularly with respect to dependent claims where the associated independent claim is rejected. That being said, as a practical matter, many believe current USPTO examination of claims is in any event similar in practice to that in the EPO with respect to treatment of dependent claims once an independent claim has been found allowable.

Issue 2: In United States restriction practice, the applicant can file a subsequent application that is directed to an invention that was divided out of the parent application. These are called Divisional applications. Divisional applications are typically subsequently filed and are not normally examined concurrently with the parent application. Divisional applications retain the benefit of the filing date of the original application if the conditions set forth in 35 U.S.C. 120 are met. This allows an applicant to continue to pursue protection for the inventions subject to restrictions that were in the original application without being affected by double patenting. All member states of the Paris Convention for the Protection of Industrial Property (1967) (including Japan and all EPC member states), as well as the EPO, also provide for the filing of Divisional applications. However, the PCT does not yet provide for the filing of Divisional international applications. Consequently, the PCT rules provide for applicant to pay for the search and examination of additional inventions that "lack unity" in a single international application. Adoption of a Unity of Invention standard could, in some instances, require examining more inventions during the examination of a single application than occurs presently, thereby possibly causing delay in the examination of other applications if examination resources are limited. This could increase the USPTO's average patent pendency time.

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 that lack Unity of Invention in the same application?

**COMMENT:** Regardless of whether it adopts a unity of invention standard, the USPTO should seize every opportunity presented by implementation of the 21<sup>st</sup> Century Strategic Plan to reduce the burden on applicants from restriction practice and find ways to examine related claims in a single application. Concurrent examination of claims directed towards related inventions in a single application should increase the overall

efficiency of the examination process, for both applicants and the USPTO, as opposed to sequential examination of restricted inventions in divisional applications with associated redundant procedural requirements. Current divisional application practice theoretically provides an effective means for prosecution of truly independent and distinct claimed inventions disclosed in a single application, where there would be no efficiency gained from the concurrent examination of such unrelated inventions. However, when claimed inventions are related in some manner, an option of paying additional search and/or examination fees should appeal to many applicants as a reasonable alternative to divisional applications to have such related inventions examined efficiently in a single application, provided that the fees more closely represent actual average incremental cost and are not merely a multiple of the statutory application filing fee for the number of alleged "independent and distinct" inventions.

It is noted that any "additional invention fee" should reflect actual average incremental costs associated with examination of an additional related invention. Accordingly, to the extent any "additional examination and/or search fees" may be adopted for examination of claims that lack the required unity, such fees should be coordinated with any other excess claim fees charges (i.e., applicants should not be charged beyond the actual reasonably anticipated costs for examination of additional claims).

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?

**COMMENT:** NO. It is considered speculative at best to think such change (examining related invention together, rather than requiring separate examinations) would have a significant negative impact on "actual" pendency of claimed subject matter. Rather, it is believed that an additional fee procedure could improve overall examination efficiency, e.g. by eliminating repetitive administrative procedures in multiple divisional applications.

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?

**COMMENT:** NO. IPO believes the basis for this question is speculative and the effect could be just the opposite, i.e. that overall examination delays will be mitigated.

Issue 3: Under the PCT, examination proceeds on the basis of the first claimed invention if applicant does not pay for additional inventions that lack unity.

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?

**COMMENT:** Under any standard or procedure adopted, the applicant should retain the opportunity to elect the group(s) of claims to be examined, whether as a result of an imposed restriction requirement between unrelated inventions, or as a result of failure to pay any imposed "additional examination fee" for related inventions which lack unity of invention. The more commercially important aspects of an invention may become apparent after filing. And, both the public and the applicant benefit when claims to all of the more commercially important aspects of an invention are examined initially and together. Providing this option, which can be exercised in most cases through a telephone call, imposes, at worst, minimal cost or delay for the USPTO.

Issue 4: A determination of lack of Unity of Invention is predicated on assessing whether a common feature (referred to as a "special technical feature" in the context of PCT Rule 13) defines a contribution over the prior art. Certain PCT member states assess this requirement only with respect to patentable advances over prior art. However, issues of lack of support, enablement, clarity, or conciseness, generally resulting from excessive breadth of claims or excessive numbers of claims, may occur that render examination unduly burdensome. In such circumstances, some International Authorities will make a "partial search" declaration to limit the extent of search and examination. The USPTO does not follow this practice. On the other hand, it may be viewed that if the common feature or "special technical feature" is not adequately supported by the disclosure or lacks utility ("industrial applicability" in the PCT context), the special technical feature does not make a contribution over the prior art.

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?

**COMMENT:** NO. First, the statement that "the USPTO does not follow this [partial search] practice" is believed by many practitioners to be more of a stated policy than standard practice, e.g. when examiners are unable to understand the scope of a claim clearly defined by terms of art that may be unfamiliar to an examiner who is constrained by time to read a lengthy detailed description.

To address this issue, the IPO believes that search practices should not be "limited" in any new way under an "unduly burdensome" rationale. It is believed that the most efficient way to examine claims is to first focus on novelty before other bases for patentability such as enablement or definiteness is addressed. Issues on non-novelty conditions for patentability can change if the scope of claims is narrowed to meet the novelty condition. Addressing non-novelty conditions out of order would be inefficient practice.

Alternatively, should the USPTO assess adequacy of the disclosure and industrial applicability in addition to the prior art when determining whether the claims' common features makes a contribution over the prior art?

COMMENT: NO. Adequacy of disclosure is an element of 35 U.S.C. 112 and should be addressed only with respect to enablement and written description. Industrial applicability is a condition of patentability. The issue seems to confuse initial review for unity of invention with substantive patentability examination.

Issue 5: The USPTO's 21<sup>st</sup> Century Strategic Plan is predicated on a certain level of revenue to provide the resources needed to meet quality and timeliness goals. The Plan currently does not account for any additional resource requirements, and any corresponding revenue shortfalls, that may result from adopting a Unit of Invention standard. Statutory fees under 35 U.S.C. 41(a) and (b), in the aggregate, are set to cover USPTO operating costs. If the average cost of processing patent applications goes up, the USPTO will need to increase fees. Assuming that there will be extra costs of examination under Unity of Invention, possible increases would be: (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) through (4) above.

Which of the above approaches should the USPTO propose in regard to any fee increases?

**COMMENT:** The USPTO should not adopt a unity of invention standard unless its study reasonably predicts an increased quality of patents while maintaining overall examining costs at about the same level. It is noted that an increase in costs from adopting a unity of invention standard is speculative and not inevitable. Alternatives for correcting faults of the current restriction practice should be examined and the projected consequences for quality and costs compared with the current system and projections for unity of invention. It is further noted that adoption of creative examination procedures to deal with related inventions in a common application with reasonable additional search and/or examination fees should benefit both the USPTO and applicants by reducing overall costs, significantly reducing actual pendency and issuing higher quality patents.

It is further noted that any shortfall of revenue that might result from issuance of fewer patents as a result of adoption of unity of invention, if at all, would not occur for at least four to eight years. This might be offset by other factors. If a real shortfall actually developed, Congress could consider general increases in user fees in line with usual procedures.

Issue 6: Adopting a Unity of Invention standard would impact the number of inventions that would be examined in a single application, and require examining multiple inventions that cross multiple disciplines in a single application. Due to the current level of technical specialization in the Patent Examination Corps, the USPTO will have to consider the impact any change would have on the ability of the USPTO to maintain high quality examination.

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 section 705 of the Manual of Patent Examining Procedure (8<sup>th</sup> ed. 2001) (Rev. 1, Feb. 2003); (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?

**COMMENT:** IPO believes that the technical specialization of most Examiners is not so narrow that they are unqualified to efficiently examine related inventions that cross multiple disciplines in a single application once a search is completed. An option for payment of an "additional invention fee" to have inventions that lack unity of invention searched and examined in a single application should be limited to related inventions that lack unity of invention (i.e., truly unrelated inventions should still be subject to restriction without any opportunity to pay an additional invention fee for consideration in a single application). This should minimize any impact on the technical specialization in the Patent Examination Corps and allow most applications to be handled by a single examiner in accordance with present practice. Where expertise is nonetheless found lacking, the suggested options could be explored.

Issue 7: One way of adopting aspects of Unity of Invention without making any statutory changes would be for the USPTO to use its authority under the continued examination provisions of 35 U.S.C. 132(b) (authorizes request for continued examination or RCE practice) to permit applicants to pay an RCE fee and submit or rejoin claims to additional inventions after 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. In this option, most applications will continue to be examined under the USPTO's current restriction practice. Under any new provisions to implement this option, when a claim is determined to be allowable, the applicant would be entitled to request continued examination under the Unity of Invention standard. The required submission would be additional claims that either depend from or otherwise include the features of the earlier-examined claims that are in condition for allowance (if such additional claims were not previously pending in the application).

Should the USPTO consider this option?

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?* 

**COMMENT:** IPO does not believe many applicants would prefer this approach over currently available choices, e.g. filing of a divisional application or requesting rejoinder of linking claims without the need for filing an RCE. To the extent the USPTO may allow for withdrawn related inventions to be rejoined beyond what may be done under current practice, it is still believed to be more efficient to examine such additional

claims contemporaneously with related claims rather than sequentially. Regardless, some applicants may choose such an option if made available to reduce maintenance fees.

IPO believes that all applications should be published. This would facilitate applicants' own prior art searching to assure issuance of patents with enforceable claims.

Issue 8: As a second example of adopting aspects of Unity of Invention without making any statutory changes, the USPTO could use its authority under continued examination to permit requests that the USPTO continue examination of claims which were withdrawn from consideration. This option would require applicants to make a decision to request continued examination rather than file a divisional application, to pay a fee for the treatment of one additional invention, and to present claims drawn only to that additional invention. This option would be available in addition to the continuing option of filing a divisional application.

Should the USPTO consider this option?

If so, how should the loss in issue and maintenance fee collections be offset relative to the current structure?

**COMMENT:** IPO views issue 8 to be essentially the same as issue 7 with respect to proposing an approach that does not appear to reduce the burden of restriction practice.

Issue 9: In view of the previous questions and the range of issues and options, 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)?

**COMMENT:** It is premature to discuss whether or not changes to the statute might be required if the USPTO were to adopt some version of the unity of invention standard in place of current restriction practice. The current language may or may not accommodate such a change. However, until the consequences of quality and cost of such a change and the basic framework are adopted, this question should be set aside for later review.

IPO does endorse a study to modify current restriction practice to prohibit restriction between related inventions in combination with an option for applicants to pay additional search and/or examination fees for examination of such related inventions in a single application. Again, any "additional invention fee" should reflect actual average incremental costs associated with examination of any additional related inventions. Such a business-like practice would be the most expedient and effective way to address many of the current concerns of USPTO customers. The only required statutory change would appear to be with respect to 35 U.S.C. 41 (i.e., an added provision authorizing the PTO to

impose such an additional invention fee for search and/or examination of multiple related inventions in a single application). 35 U.S.C. 121 itself would not need to be amended, as such section gives discretion to the Commissioner whether restriction between independent and distinct inventions is to be required or not.

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

**COMMENT:** It is believed that many, but by no means all, of the perceived problems with respect to unreasonable restriction practice requirements could be addressed simply by the USPTO monitoring and enforcing adherence to the existing requirements (i.e., claims must be drawn to independent and distinct inventions and there must be a <u>substantial</u> burden to examine together). Changes might be largely unnecessary if the PTO charged its examiners to seek to hold related claims in a common application rather than endorse restriction to excessive limits.

In this regard reference is made to the Decision of the Commissioner in *In re Application of Caterpillar Tractor Co*, 1985 Commr.Pat. 6, 228 USPQ 77, where the Commissioner in defending a refusal to adopt unity of invention reported on a remedial program during the years 1984 –1985 in which USPTO-initiated efforts to reduce the number of unreasonable restriction requirements resulted in a greater reduction of "reasonable" restriction requirements.

Applicants who seek patents on inventions characterized by Markush groups, or DNA/amino acid sequences or both are faced with particularly difficult situations. Such applicants find restriction practice applied not only among claims but within a single claim (see MPEP 803.04) even though some argue the courts have declared that the USPTO has no authority to do so. See *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA, 1978) and *In re Weber* 580 F.2d 455, 198 USPQ 328 (CCPA 1978). More specifically, intra-claim restriction is applied to biotechnology inventions where a single claim characterized by multiple DNA or amino acid sequences may be restricted to a single sequence for examination. While such single sequence restriction practice may be properly applied when the claimed inventions are directed towards unrelated compounds. per se, that are being characterized by DNA or amino acid sequence, such restriction practice destroys any chance for reasonable claim scope when applied to, e.g., (a) a claim to related compounds characterized by a Markush group of DNA sequences, (b) a claim to a process having a step characterized by use of any of a group of DNA compounds, and (c) a claim to a manufacture having an element characterized by any of a group of DNA compounds. It is not apparent, therefore, that a unity of invention approach necessarily would address all of the concerns of the biotechnology community.

To illustrate the problem, consider a claim to a manufacture, i.e. a microarray hybridization chip having hundreds of independent DNA elements, each of which can be characterized as a fragment of a full gene DNA sequence and each of which has the utility of diagnosing a separate hereditary disease. Under the current single sequence

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restriction practice, simply because DNA sequence is used to characterize the invention, such a claim is restricted to one of 100 independent and distinct inventions. An applicant is forced to elect to have searched and examined a claim to a microarray hybridization chip having a single DNA element characterized by a single DNA sequence. To fully claim the invention, which can be a single product of commerce, an applicant is required to file 100 patent applications. From the published request for comments, it is not clear the USPTO would apply a common feature unity of invention standard in a different manner than the current single sequence restriction practice.

The USPTO is concerned about an undue search burden, but in less than twice the time for the USPTO to prepare, search and analyze a search of its databases for a single sequence biotechnology applicants can prepare, conduct and analyze a search of the public databases for each of the 100 DNA sequences. It is true that the USPTO search is extended to both public databases and USPTO databases that include non-published sequence from US-only patent applications, but the increased burden on the USPTO is not equivalent to the increased burden on applicants for an inordinate number of additional applications.

Applicants in the "unpredictable" arts, e.g. biotechnology, chemistry and pharmaceutical fields, are burdened in ways that may be foreign to applicants in the more predictable arts. Applicants in these unpredictable arts are burdened by a need to demonstrate enablement and written description in a more detailed manner resulting in very lengthy applications. Biotechnology applicants have expressed concern that adoption of a unity of invention standard in practice might become merely the restriction tiger with changed stripes. What applicants want is an examination practice for the full invention as claimed at an appropriate price. Adoption of an incremental search and examination fee practice would go a long way to satisfying all applicants burdened by restriction practice.

While restriction practice has been traditionally more of a concern to practitioners in the unpredictable arts, applicants in the so-called predictable arts also have been experiencing more frequent restriction and election of species requirements during prosecution. There has been an increasing number of restriction requirements in such arts where claims are each identified as a separate species as to which an election must be made, or where restriction requirements are made based upon "species" identified by the examiner from sub-parts of claims or from the specification even where the identified subject matter has not been separately or individually claimed by the applicant. Given the burden placed upon applicants that any subject matter disclosed but not claimed may be dedicated to the public, this trend may force applicants even in the predictable arts to file more claims, and to file more divisional applications, to the detriment of efficiency of the examining process and the objectives of the Strategic Plan.

In its study of a unity of invention standard the USPTO must consider how such a standard would provide an Examiner with the tools, (e.g. published guidelines and a fair fee structure) and motivation (e.g., a flexible appraisal system) that will encourage a quality examination of a complete invention that is fair to all applicants.

We commend the USPTO for undertaking this study of a very difficult subject. Our letter expresses the positions of IPO at this time. We look forward to learning from your study, and will review or supplement IPO positions as additional information becomes available.

Sincerely,

/S/ Herbert C. Wamsley Executive Director