Comments of the United States of America Regarding the Working Group on Multiple Invention Disclosures and Complex Applications

General Comment:

The United States of America appreciates the time and resource limitations on the Working Group and the Standing Committee on the Law of Patents (SCP) as a whole, in particular with respect to such complicated and comprehensive subject matter. Therefore, we fully support maximizing the use of the SCP electronic forum, as suggested by the International Bureau, in order to achieve a more efficient sharing of information, particularly at the preliminary stages of this Working Group. However, we should bear in mind that comprehensive harmonization on this complex topic may require increased time allocation for the Working Group as its discussion evolves.

The electronic forum would appear to be very helpful with respect to survey information, with particular respect to those members either currently having or having had experience with methods of limiting claiming that vary from the "Unity of Invention" standard as it is known in the PCT. If the SCP forum is considered to be appropriate for such use, the United States would be happy to provide an overview document of the "independent and distinct" restriction practice currently found in our laws, regulations and practice guidelines.

Specific Comments – Issues Identified by the International Bureau

(1) Unity of Invention

While the "unity of invention" standard is entrenched in the Patent Cooperation Treaty (PCT) and many national offices around the world, we have concerns that this standard is outdated in light of the advancements in innovative fields. Further, in a broader sense, the "unity of invention" standard and its reliance on "special technical features" that define a "contribution over the prior art" appears to be a standard that does not conform to the four factors set forth in document SCP/6/6 – and should therefore be reexamined.

Those factors are: (1) reducing the burden on the examiner; (2) focusing the prosecution of an application on a single, yet entire, invention; (3) developing a practice for limiting claiming that is easy to understand, can be applied consistently in practice, and is fair to the applicants; and (4) considering the long-term viability of these practices.

For example, there are significant search requirements imposed on the patent examiner before a determination under the "unity" standard can be made. This results from the very definition of "special technical feature" as used in the PCT.

The United States believes that the patent system would be better served, for both applicants and examining offices, by a system that would provide for a final determination of claim limiting (whether termed "unity of invention" or not) that can be made *a priori* with respect to searching on the sole basis of the language of the claims as presented, to the extent that this is feasible. This would be a significant change not only from the PCT "unity" practice, but additionally certain aspects United States national practice. However, it is a topic that we feel is worth the SCP exploring.

Such a system would meet the goals of the four factors listed previously, in reducing burdens of searching and, possibly, re-searching burdens on the examiner due to *a posteriori* considerations of unity or restriction, as well as clarifying the process for applicants. If the standard is based on the claims as presented, it would be easier for applicants to determine appropriate subject matter for a particular application, thereby reducing the need for restriction of claims in the first place.

The "unity of invention" standard as it is currently defined in the PCT also presumes the existence of a single, easily recognizable special technical feature among different inventions. Our experience has indicated that this presumption does not always bear out in many applications, and identification of a single technical feature may require a considerable amount of analysis. This standard also fails to treat claimed inventions "as a whole," which is a more appropriate methodology for viewing claims in the examination process.

Additionally, the "special technical feature" standard, as it merely defines any advance over the art, may result in the combination, in a single application, of inventions drawn to distinct areas of art that would otherwise be separated into groups that could be searched and examined better and more quickly by examiners with technical proficiencies best suited to each distinct area of art. Quality of examination, effective classification and dissemination of technology, and efficiency appear to suffer as a result.

We also would like to note that differing views on this topic, as well as the topic of permitting certain types of multiple dependencies of claims, may be interrelated with the different practices among offices regarding the treatment of dependent claims. The United States believes that dependent claims should be examined fully and separately, i.e., as an independent claim containing all the limitations of the claim from which it depends. Due to the interrelation of this issue to the overall goals of the SCP, the Working Group should consider the issue of varying treatment of dependent claims by different examining offices.

(2) Linking of Claims

The USPTO has significant experience with what we term "linking claims." While we are currently looking for ways to improve this practice, with respect to the goal of restriction based solely on claims presented as stated in our comments to paragraph

(1), our experience with this subject matter may nonetheless be useful to the SCP in determining ways of reducing search burdens. There are a number of situations where an application has claims to two or more inventions which would be properly divisible in accordance with USPTO restriction practice and additionally has one or more generic claims, sometimes called "linking" claims, that are inseparable from, and thereby link, the otherwise divisible inventions together. In such a case, the patent examiner may make and maintain a restriction requirement between the properly divisible inventions so long as the linking claims are not considered free of the prior art.

The most common types of linking claims that, if allowed, act to prevent restriction between inventions, or to require withdrawal of a previously made restriction requirement, are the following:

(A) a genus claim linking species claims;
(B) a claim to the necessary process of making a product linking proper process and product claims;
(C) a claim to "means" for practicing a process linking proper apparatus and process claims; and
(D) a claim to a product linking a process of making and a process of using the product.

Under current USPTO procedures, the patent examiner will make a restriction requirement between the patentably distinct inventions and will clearly indicate to the applicant which claims are linking claims. Upon election by the applicant, the linking claims will be examined with the specific invention elected. When the linking claims are rejected, all claims not readable on the elected species are withdrawn from examination consideration. However, whenever a linking claim is found to be free of the prior art, based on the initial examination, even though it may be objected to or rejected merely on formal grounds, the restriction requirement must be withdrawn with respect to any claims that fall within the scope of the linking claim.

Any claim directed to a non-elected invention, previously withdrawn from consideration, which depends from or includes all the limitations of the linking claim that is free of the prior art must be rejoined and will be fully examined for patentability. Therefore, United States restriction practice with respect to linking claims is search dependent and may create a "rolling search" of the linked inventions.

We are currently looking for ways to improve this practice, with respect to the goal stated in our comments to paragraph (1). However, this procedure may be considered useful in reducing the search burden on patent examiners in that while distinct inventions are "linked" (and may thereby share certain features), it will limit the search only to particular embodiments until the linking claim is determined either to be free of the prior art, in which case the search is then extended until all claims which depend from or include all the limitations of that linking claim are searched, or the linking claim is determined to be unpatentable.

(3) Number of Claims

Arbitrarily limiting the number of claims would be very controversial with patent applicants and other user groups. Indeed, limiting the number of claims arbitrarily may force applicants to file additional applications with claims directed to essentially the same invention. If applicants are not allowed to do so, as any system for limiting claiming should ensure that two patents are not granted for the same invention, they may not be able to fully claim their invention.

An unintended consequence of this type of limitation may be the proliferation of applications on the same subject matter. This could lead not only to multiple patents for the same invention, but to an increase of patent applications in general thereby increasing backlog and work-load burdens, rather than decreasing them. If applications claiming very similar subject matter are assigned to different examiners, there may also be a duplication of effort involved in the examination of these applications.

However, the USPTO observes that limitation by number on independent and distinct *embodiments* could be useful in certain applications. Exploration of this concept may be valuable with respect to "Markush" groupings or other large groupings of independent "species" inventions, particularly if "linked" by some special feature that may be generic to all.

(4) Requirement of "Clear and Concise" Claims

The requirement that claims be "clear and concise" may have an aspect related to unity or restriction type practices. In particular, the requirement of clarity and conciseness of claims "in their totality" appears to be directly related to this issue. Indeed, Note 11.03 of document SCP/6/4 declares that "undue repetition of words or a multiplicity of claims of a trivial nature, which render it unduly burdensome to determine the matter for which protection is sought, could be considered as not complying with this requirement."

It appears then, that this requirement may relate to undue numbers of claimed embodiments, or even, in certain circumstances, that sheer number of claims could result in a collection of claims deemed unclear as a whole. This standard should be more fully discussed with respect to these aspects in the Working Group. However, aspects dealing with the clarity of scope of individual claims, and similar issues, should be left to the Committee at large.

(5) Special Procedures to Treat Complex Applications

Examining offices have seen a significant increase in the complexity of patent prosecution with respect to certain fields of innovation. We recognize that there are particular areas that may require unique solutions. While, for the most part, these

solutions should be dealt with as part of an overall scheme, the USPTO has specifically addressed the issue of nucleotide sequences in claims.

Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141 *et seq*. Nevertheless, in 1996, the USPTO decided to partially waive the requirements of 37 CFR 1.41 *et seq*. and permit a "reasonable" number of such nucleotide sequences to be claimed in a single application. However, the USPTO has struggled to determine what would constitute a reasonable number of such nucleotide sequences to be claimed in a single application so as not to create an unreasonable burden on USPTO resources.

In 1996, the USPTO initially determined that ten sequences would constitute a reasonable number for examination purposes. However, over the past few years, the examination of as many as ten sequences per application has not proven to constitute a "reasonable" number for examination purposes. Currently, restriction to a single sequence is not uncommon. Examination of multiple independent and distinct nucleotide sequences, in many applications, may pose an unacceptable examination burden. These applications, as well as those in other emerging technologies, may be causing unique examination issues that should be addressed, as appropriate, by the Working Group.