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From: Jackson, Jimmy
Sent: Friday, September 08, 2006 3:07 PM
To: AB95 Comments
Subject: Comments on proposed changes

Please see attached comments

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BIOCOM

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

BIOCOM appreciates the opportunity to provide comments on the Proposed Changes to Information Disclosure Statement Requirements and Other Related Matters, Notice of proposed rulemaking (the "Notice") as published in 71 Fed. Reg. 38808 (10 July 2006).

BIOCOM is a regional advocacy organization representing more than 500 dues paying life science companies and service providers in Southern California. Strong intellectual property protection is important to attract the substantial investment required to bring new life-saving therapeutics to the market. Toward that end, BIOCOM and its member companies have a keen interest in potential changes to the patent examination process which may increase the cost of obtaining patents, increase the risk of challenge to the resulting patents, and consequently reduce the ability of small companies which do so much of the innovative research in this country to raise the capital necessary to pursue their goals.

BIOCOM supports the goal of improving patent examination by the United States Patent and Trademark Office (USPTO). However, the proposed changes contained in the Notice warrant a closer look and some fine tuning.

Three major changes are proposed in the Notice with respect to the submission of Information Disclosure Statements. An added statement as to the relevance of a reference will be required under any one of three circumstances:

1) More than 20 references are submitted;
2) Any reference is greater than 25 pages long; or
3) Any reference is in a foreign language.

Let us consider the propriety, and possible impact, of each of these parameters. With respect to point (1), the threshold of 20 references submitted to trigger the presentation of an added statement is arbitrary. In some technologies, one would never expect to reach this threshold, whereas in other technologies (e.g., biotechnology), one would rarely expect to remain below this threshold. To impose an added burden in such a way as to prejudice certain classes of patent applicants (e.g., life science companies), with little, if any, impact on other classes of patent applicants, is inherently unfair.

Indeed, placing a limit on the number of references submitted by an applicant is counter-intuitive for several reasons. First of all, applicants should be encouraged to disclose all documents which are potentially relevant to the claimed invention. Contrary to this goal, this proposal has the effect of discouraging disclosure in order to avoid the added burden, and to

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avoid cluttering the record with additional discussion of prior art which should speak for itself. Moreover, by discouraging patent applicants from disclosing all potentially relevant prior art of which they are aware, the USPTO is actually placing more of a search burden on patent examiners. Potentially relevant prior art does not go away just because the USPTO would like to streamline the amount of prior art that an examiner may need to consider. The USPTO cannot bury its head in the sand, instead, it must embrace the increasing amounts of prior art that are made readily available by modern means of communication, such as the internet.

With respect to point (2), the 25 page threshold is arbitrary—failing to take into account the true content and size of a document. Indeed, the proposed page limit is an unduly short threshold for many forms of publication. A type-set journal publication, for example, would rarely approach 25 pages in length, whereas a published PCT application, especially in the life sciences field, would very commonly exceed this arbitrary threshold. Besides, regardless of the characterization provided by an applicant, it is still incumbent on the Patent Examiner to independently review the reference and evaluate the possible relevance thereof.

Furthermore, the proposed page limit is inherently unfair as it will have a disproportionate impact on selected technologies, such as life sciences.

To the extent that the imposition of a requirement for an added statement as to the relevance of a reference is to be based on the size of a document, it would be appropriate to set the page limits based on the type of document. Thus, a more realistic threshold for non-patent literature would be 25 pages, while a threshold of 50 pages (exclusive of drawings, sequence listings and claims) would be appropriate for United States Patents and published Patent Applications, and 100 pages for a published PCT application (exclusive of drawings, sequence listings and claims).

With respect to point (3), it would be helpful for the nature of the "additional disclosure" required by the USPTO to be clarified. Many times, it is a figure or a graphic in a foreign language reference that appears relevant to the claimed invention. This would be as readily apparent to the Patent Examiner as to any patent applicant who also did not speak or read the particular foreign language involved. Without further clarification as to what is acceptable, the proposed requirement is unduly vague. Applicants should not be exposed to a new requirement without being clearly informed as to how that requirement can be met.

As an alternative to the presently proposed rule change—it is proposed that, in recognition of the additional work required by a Patent Examiner to dispose of highly complex subject matter (as reflected, for example, by the existence of a large number of potentially relevant references for the Examiner's consideration), the USPTO should develop standards which provide enhanced credit to Patent Examiners for disposal of such highly complex subject matter. In conjunction with the granting of such enhanced credit, to the extent that submission of an Information Disclosure Statement which exceeds any of the thresholds set forth in the Notice places an added burden on the Patent Examiner, it is suggested that this added burden be addressed by assessing a one time fair and reasonable "excess reference" fee against the applicant in a manner similar to the requirement to pay excess claim fees upon submission of an application containing a greater number of claims than are embraced by the basic filing fees.

Such a fee would only be assessed against the first case in a family of related cases (e.g., continuations, divisionals, and the like) in which the fee may apply.

BIOCOM believes that the disproportionate added burdens of the proposed rules on life science companies will dramatically reduce the ability of smaller companies (who make up the majority of BIOCOM's membership) to file and prosecute patent applications. Moreover, the additional disclosure requirements will subject the patent portfolios of BIOCOM members to added scrutiny, with the potential to significantly reduce the ability of BIOCOM members to raise the capital necessary to pursue their goals.

BIOCOM appreciates the opportunity to comment on the proposed changes and to suggest alternative approaches to addressing USPTO concerns. BIOCOM welcomes the opportunity to work with the USPTO to develop a fair set of rules regarding the submission of Information Disclosure Statements that address USPTO concerns without unduly increasing the costs and risks inherent in the exercise of obtaining patents.

Respectfully submitted,

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