-----Original Message-----From: Gritzmacher, Christine

Sent: Friday, September 08, 2006 1:39 PM

To: AB95 Comments

Subject: Proposed changes to IDS requirements

The following comments and questions are submitted for consideration with regard to the proposed "Changes To Information Disclosure Statement Requirements and Other Related Matters" that appeared in Fed. Reg., vol. 71, No. 131 (July 10, 2006).

1. Threshold number of cited information

A maximum of 20 documents in IDS submissions in the "First time period" without requiring additional explanation seems arbitrary and likely to affect certain technology areas more than others. The justification for this number, based on survey results (85% of surveyed applications cited 20 or fewer documents, and 81% cited 15 or fewer documents) "across all technologies" does consider technology fields that are more crowded resulting in more available relevant art, or the level of complexity of an invention which influences the amount of relevant prior art. For example, a chemical invention for a lubricant consisting of two known compounds differs significantly from a chemical invention for a pharmaceutical that encompasses on a generic compound, and the relevant prior art for the former invention would likely be significantly less than cited in the latter application.

Therefore, I suggest that the threshold number of documents be increased, e.g., to 50 documents.

2. Page length of cited documents

The requirement of an explanation for all documents over 25 pages cited in the "First time period" appears arbitrary and likely to selectively affect applicants in certain technology areas. The page size of a cited document is often related to the technology area, e.g., most published patents or applications in biotechnology or chemistry areas are longer than those in simple mechanical areas. Also, the length of a cited document may be arbitrarily determined by the applicant's formatting. For example, a published patent application containing 16 pages of text and 10 figures may be 26 pages in length (requiring an explanation) if each figure is presented on a single sheet, whereas the identical disclosure may be 21 pages (not requiring an explanation) if the figures are presented as 2 figures per sheet. Allowing an applicant to submit only a portion of a document where only a portion of a document is relevant to the claimed invention does not cure the problem if the entire document is considered relevant.

Therefore, I suggest that the page length that determines whether a cited document requires an explanation be increased to over 50 pages.

3. Explanations required for long documents, foreign-language documents, or a large number of documents.

Clarification is requested for proposed section 1.98(a)(3)(iv) in view of the comments in the Federal Register (July 10, 2006) regarding the additional disclosure requirements. The comments state that "in appropriate cases applicants must provide additional disclosure, such as an identification of how the specific feature, showing or teaching of the document correlates with language in one or more claims" or in certain circumstances "correlation to a specific portion of the supporting specification" (Fed. Reg. 71(131), pg. 38810, col. 2, para. 2.) In contrast, the proposed additional disclosure requirement for the First time period under section 1.98(a)(3)(i)(3), in accordance with proposed 1.98(a)(3)(iv), is to provide "identification of at least one portion causing the document to be cited, including a specific feature, showing, or teaching, and correlation to specific claim language." This does not include an explanation of "how" the feature, showing, teaching correlates.

In either case, the proposed requirement appears to place the burden of examination on the applicant rather than the Office, because it may require the applicant to describe "how" the feature, showing or teaching of the cited document correlates with the claim language. Alternatively, the requirement places the burden of examination on the applicant because it requires an explanation of the cited portion (i.e., an interpretation of the document) and its correlation to "specific claim language." The statements that appear in Fed. Reg. 71(131): 38815, col. 1, para. 2 to col. 2, para. 1, further support the argument that the additional requirements proposed under section 1.98(a)(3)(iv)(B) place the burden of examination on the applicant. The burden of examination is clearly the duty of the Office.

I suggest that the additional disclosure requirement triggered by submission of the threshold number of documents in the First time period to only require a correlation of a cited portion(s) of a document with the claim(s) to which the portion is relevant, as identified by claim number(s), rather than claim language. That is, the applicant provides neither an interpretation of the cited portion nor an explanation of how the cited portion correlates with the claim language. Thus, examination of the claims in view of the relevant portion remains the responsibility of the Office.

4. Updating previous IDSs under section 1.98(a)(3)(ix)

Proposed section 1.98(a)(3)(ix) requires updating previous IDSs for amendments affecting the scope of the claims, other than examiner's amendments. Failure to update an explanation or state that updating is unnecessary may result in a reply containing the amendment to be treated as not fully responsive.

This requirement puts the burden of examination on the applicant. Once a document has been submitted, with or without an explanation, the applicant should have no further responsibility to update a previous IDS in view of amendments made during prosecution. The Examiner during prosecution should be aware of the cited art and the amendments and should perform the examination appropriately without further explanation or interpretation from the applicant.

5. Cumulative Art and "Non-cumulative descriptions" for Documents in the Second to Fourth Periods

Clarification is requested on what constitutes adequate disclosure under the duty of candor, what are considered "cumulative" documents, and the proposed "non-cumulative description" requirement. (See Fed. Reg. 71(131), pg. 38810, col. 2-3, and pg. 38815, col. 2, para. 2 et seq. regarding proposed section 1.98(a)(3)(v).)

- 1) Is an applicant's citation of <u>one</u> issued US patent in a patent family considered sufficient disclosure to fulfil the duty of disclosure, or must all members of a patent family, including applications that claim priority to an issued patent, be disclosed? For example, an application that claims priority to a cited patent may publish during the Second, Third, or Fourth time period of a pending application. Members of a patent family that are continuation or divisional applications presumably have identical disclosures in the specification, but include different claims. Do the different claims make these related patents non-cumulative documents that should be disclosed with a "non-cumulative description"? If the documents are considered cumulative, which member of a patent family suffices to fulfil the duty of disclosure (e.g., earliest issued, last issued, last published)?
- 2) If a US patent, a related PCT application, and a related European application exist, is citation of <u>one</u> of the documents considered sufficient disclosure to fulfil the duty of disclosure, or must all three documents be cited? Presumably, there is "substantial overlap" between the disclosures but the claims may differ (e.g., a "feature" in a US patent claim may not appear in the European patent application's claim). Would these related documents be considered non-cumulative that should be disclosed with a "non-cumulative description"? If the documents are considered cumulative, which one suffices to fulfil the duty of disclosure?

Respectfully submitted, Christine Gritzmacher Gen-Probe Incorporated