-----Original Message-----
From: mike.m.strickland@gsk.com
Sent: Friday, September 08, 2006 3:16 PM
To: AB95 Comments
Subject: Comments on Changes to IDS Requirements . . . .

Dear Mr. Bernstein,

Attached please find the comments of GlaxoSmithKline on the Notice of Proposed Rulemaking entitled "Changes to Information Disclosure Statement Requirements and Other Related Matters", published Monday July 10, 2006 in the Federal Register, Vol. 71, No. 131, pages 38808 through 38823.

GlaxoSmithKline appreciates the opportunity to comment on the proposed rules.

Best regards,

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline

Comments on Proposed Changes to Information Disclosure Requirements and Other Related Matters

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

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

Attn: Hiram H. Bernstein
Senior Legal Advisor
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Information Disclosure Statement Requirements and Other Related Matters"
71 Fed. Reg. 38808 (July 10, 2006)

Dear Under Secretary Dudas:

In response to the Proposed Rulemaking published July 10, 2006, at Federal Register, Vol. 71, No. 131, p. 38808-38823, GlaxoSmithKline ("GSK") submits the following comments.

Executive Summary:

The Patent Office has proposed various changes to the current Information Disclosure Statement (IDS) requirements to improve the quality and efficiency of the examination process. As one of the world's leading research-based pharmaceutical and healthcare companies, GSK has a keen appreciation for the importance of a strong and effective patent system that efficiently produces patents of the highest quality.

From the Patent Office's comments in the proposed rulemaking, it appears that the Office is attempting to address two primary concerns through the rulemaking: (1) the burden placed on the Office by the improper citation of cumulative and/or irrelevant references; and (2) the burden placed on the Office by the proper citation of lengthy and/or numerous references.

To the extent the Patent Office is concerned about the excessive citation of cumulative or irrelevant references, the Patent Office acknowledges in the rulemaking that examiners already have the tools necessary to address such circumstances by indicating to the applicant that the IDS is not compliant with the current IDS requirements. Accordingly, GSK believes that the imposition of additional rules and disclosure requirements is not required to address this concern.

To the extent the Patent Office is concerned about the time burden placed on an examiner when a large number of references is submitted legitimately in an application, GSK encourages the Patent Office to consider implementing an IDS fee schedule that is designed to compensate the Patent Office for the additional resources needed to review the references.

Should the Patent Office conclude that examiners do not currently have the tools necessary to address the improper submission of references and/or that a fee schedule would not adequately address the problem of large legitimate submissions, GSK encourages the Patent Office to revise the proposed rules to ensure that a better balance is struck between the burdens placed on the examiner and the burdens placed on the applicant. At a minimum, GSK submits that the following points should be considered when revising the proposed rulemaking: (1) increase the page limit for foreign patent references and translations; (2) no explanation should be needed for foreign language documents if a translation is provided, assuming the page limit requirement is met; (3) an explanation should only be required for references in excess of 20; (4) IDS requirements under RCE practice are too restrictive; (5) requirements for providing an explanation under § 1.98(a)(3)(iv) should be revised; (6) documents considered in a parent application should not count against the document limit when cited in a continuing application for the purpose of having the documents appear on the face of the continuing patent; (7) documents cited from prosecution of a related application should not count against the document limit; (8) Documents falling under § 1.98(a)(3)(viii) should be exempt from the calculation under § 1.98(a)(3)(i)(C) of the total number of documents submitted during the first time period; (9) translation requirements under § 1.98(a)(3)(xi) should be clarified; (10) whether an explanation is required for references that describe features in non-designated claims is unclear; (11) it is unclear how the rules apply to reissue applications; and (12) the non-retroactivity of the rules should be clarified.

GSK requests the Patent Office to reconsider whether the proposed rules will have their intended impact. Also, GSK asks the Patent Office to consider whether the current IDS requirements already provide examiners with the tools they need to address improper submissions, whether implementation of a fee schedule could be used to compensate the Office for the cost of considering large IDS submissions, and whether it may be time to eliminate the duty of disclosure.

If the Patent Office concludes that it is necessary to implement changes to the IDS requirements, GSK requests consideration of revisions to the proposed rules, such as those discussed below. The proposal of alternatives and revisions by GSK should not be viewed as an admission by GSK that the Patent Office has the authority to enact any of the proposed alternatives or revisions, or even that GSK views the alternatives or revisions as rendering the proposed rules acceptable. GSK reserves the right to challenge any final rules through the appropriate legal channels.

Proposed Alternatives to the Proposed Rulemaking:

GSK provides the following comments and proposed alternatives for consideration by the Patent Office in light of the Office's current concerns.

1. Reconsider whether proposed rules will have desired impact

After analyzing the proposed changes to the IDS requirements, GSK believes that the proposed rules will not improve prosecution efficiency as suggested by the Patent Office. For example, in the proposed rulemaking, the Patent Office notes that only 15% of applications are likely to be impacted by the changes to IDS requirements for submissions in the first time period; however, examiners will have to review all IDSs to ensure that they comply with the new rules. Examiners will, for example, have to review all IDSs submitted in the first time period to determine whether any cited reference exceeds 25 pages in length, inclusive of drawings, but exclusive of sequence listings or computer program listings, which would trigger the requirement to submit an explanation. Examiners will also have to analyze submitted explanations, cumulative descriptions, and patentability justifications to determine whether they are in accordance with the proposed rules. If an examiner determines that the submission is not in accordance with the proposed rules, the examiner will have to prepare a notice of non-compliant IDS with an indication as to why the IDS is non-compliant, and will then have to engage in a subsequent review of the re-submitted IDS to determine if the deficiencies have been corrected. Furthermore, nothing in the proposed rules will absolve the examiners of their responsibility to review the content and evaluate the relevance of each submitted document whether or not such documents are submitted with an explanation or other additional disclosure. Thus, all of this analysis and review will need to be done in addition to the examiner's current requirement to review all cited references. Accordingly, the proposed rules will likely increase the burden on the examiner and will not improve prosecution efficiency as suggested by the Patent Office.

2. There is no need to change the rules to address the submission of cumulative and/or irrelevant references

In the proposed rulemaking, the Patent Office goes to some length to indicate that the proposed rules are, to some extent, merely making explicit what is implicit in the current IDS requirements (e.g., applicants are already under a duty not to submit cumulative references). Thus, to the extent that the proposed rulemaking is intended to address the submission of cumulative and/or irrelevant references, it appears that the proposed changes are not necessary in view of the Patent Office's assertion that the current IDS requirements prohibit the citation of references that are cumulative and/or irrelevant. Accordingly, the Patent Office is proposing increasing the burden on both examiners and applicants to address a problem that the Patent Office admits can already be addressed by strict application of the current IDS requirements.

3. The Patent Office should consider implementing an IDS fee structure instead of adopting the proposed rules

To the extent the Patent Office is concerned about the time burden placed on an examiner when a large number of references is submitted legitimately in an application, GSK encourages the Patent Office to consider implementing an IDS fee schedule that is designed to compensate the Patent Office for the additional resources needed to review the references instead of implementing the proposed rules, which would increase the burden on examiners and applicants alike. For example, an applicant's filing fee could allow the applicant to submit a certain number of references for consideration by the Office. If the applicant found it necessary to submit a number of references that exceeded the limit, the applicant would need to pay additional fees to cover the

additional expense incurred by the Office in reviewing the additional references. In view of the Patent Office's expressed concerns regarding the difficulty the Office faces in hiring additional examiners, the Office may even want to consider an escalating fee schedule, which would acknowledge that the cost to the Office of considering a large number of references in multiple applications is not merely the cost of additional examination time, but also the cost of hiring, training, and retaining additional examiners.

4. Consider eliminating or drastically reducing the applicant's duty of disclosure

It is clear from the Patent Office's comments that the Office would prefer for applicants and examiners to work together as a team to provide the most efficient prosecution of an application. For example, the proposed IDS rulemaking states that "[e]nsuring a focused and thorough examination is a joint responsibility of the examiner and the applicant, particularly as examination is not seen by the Office as an adversarial process." Fed. Reg., Vol. 71, No. 131, at p. 38810. GSK agrees with the Office that examination, in and of itself, is not an adversarial process. Examiners want to allow and applicants want to obtain patents that are of the highest quality. However, the duty of disclosure embodied by § 1.56 transforms what should be a non-adversarial team effort involving examiner and applicant into an adversarial process because the information exchange between examiner and applicant, which produces the file history of the patent, becomes fodder for an inequitable conduct charge in one of the most intensely contested adversarial processes, patent litigation. As long as the specter of inequitable conduct hangs over the prosecuting attorney, the prosecution of patent applications will, as a necessity, remain an adversarial process. Eliminating the duty of disclosure embodied by § 1.56 would free the prosecuting attorney from this specter and go a long way toward restoring patent prosecution to a far more effective, non-adversarial process.

Eliminating the duty of disclosure is not unprecedented. As the Patent Office is aware, the European and Japanese Patent Offices operate quite effectively without a duty of disclosure. GSK suggests that the Patent Office examine European and Japanese practices to aid in determining the effects of eliminating the duty of disclosure.

To the extent that the Patent Office is concerned that completely eliminating the duty of disclosure may go to far in that it absolves applicants of disclosing information only known to the applicant (e.g., on-sale bars), the Patent Office could consider eliminating the duty of disclosure for all references and information that is publicly accessible (e.g., by publicly searchable databases).

If the Patent Office truly wants to elicit the unfettered assistance of prosecuting agents and attorneys in improving the efficiency of the U.S. patent system, GSK urges the Patent Office to examine ways of eliminating the duty of disclosure.

GSK believes that the Patent Office can accomplish its objectives of improving examining efficiency and patent quality by encouraging examiners to apply the current IDS requirements, implementing an IDS fee schedule without implementing the proposed rules, and/or eliminating the duty of disclosure. GSK encourages the Patent Office to consider these alternatives and others like them rather than adopting the proposed rules.

Proposed Revisions to the Proposed Rulemaking:

In the event the Patent Office decides to adopt the proposed rules, GSK provides the following comments and proposed revisions for consideration by the Patent Office in light of the Office's current concerns.

1. Consider increasing the page limit for foreign patent references and translations

The 25 page limit appears to be arbitrary in that it does not take into account the format of the disclosure. For example, a PCT publication is printed in a single column, double-spaced format, while US publications are printed in double column, single-spaced formats. These different formats may typically result in PCT or other foreign patent publications that are 3 to 4 times as many pages as the same disclosure printed in the US publication format. As the amount of disclosure that has to be reviewed by the Examiner is the same regardless of whether the disclosure is printed in the PCT format, for example, or the US format, it seems arbitrary that an applicant would have to provide an explanation for a PCT publication that is 80 pages in length, but would not have to provide an explanation for the same disclosure submitted as a US publication that is say 24 pages in length. In some instances, there may be no US equivalent of the foreign patent reference, so it may not be possible to submit a US publication in order to avoid having to provide an explanation.

GSK suggests that the 25 page limit be revised to include separate page limits depending on the type of disclosure being submitted. For example, the page limit for foreign patent references and translations of any foreign language document could be 80 pages, and the page limit for all other submissions including US patents, US published applications, and non-patent literature, could be 25 pages.

2. No explanation should be needed for foreign language documents if a translation is provided, assuming the page limit requirement is met

Under proposed rule 1.98(a)(3)(i)(A), an explanation in compliance with 1.98(a)(3)(iv) is required for foreign language documents. Additionally, under 1.98(a)(3)(xi) a copy of a translation of the foreign language document is required where a translation is within the possession, custody, or control of, or is readily available to any Rule 56(c) individual. Thus, as proposed, it appears that an explanation is required for a foreign language document even where a translation is provided for the document. No reasoning is given for why an explanation of a document that is, via translation, provided in English should be required, where an explanation would not be required if the document had originally appeared in English. This inconsistency appears to be arbitrary.

GSK suggests that the proposed rule 1.98(a)(3)(i)(A) be revised to provide that an explanation for the foreign language document is only required where a translation of the foreign language document has not been submitted.

3. An explanation should only be required for references in excess of 20

Under proposed Rule 1.98(a)(3)(i)(C), an explanation is required for all of the documents, if more than twenty documents are submitted, calculated cumulatively,

during the first time period. It appears that this rule is designed to reduce the Examiner's workload by forcing the applicant to submit an explanation for all documents if more than 20 documents are submitted during the first time period. However, this proposed rule appears to go too far by requiring an explanation for all 21 documents if applicants submit a 21st document, even though the submission of an explanation with only the 21st document would be sufficient to reduce the additional burden on the examiner. There may be a point where the number of documents submitted during the first time period becomes so significant that the increased burden on the Examiner justifies requiring an explanation for all documents submitted during the first time period, calculated cumulatively.

GSK suggests that Rule 1.98(a)(3)(i)(C) be revised to provide that an explanation is only required for any documents in excess of twenty submitted, calculated cumulatively, during the first time period. Alternatively, GSK suggests that Rule 1.98(a)(3)(i)(C) be revised to provide that (1) an explanation is required only for any documents in excess of twenty, if up to forty documents are submitted, calculated cumulatively, during the first time period; or (2) an explanation is required for all of the documents, if more than forty documents are submitted, calculated cumulatively, during the first time period.

4. IDS requirements under RCE practice are too restrictive

Under the proposed rules, Section 1.97(b)(4) is proposed to be deleted, such that any IDS filed with a request for continued examination (RCE), or after an RCE is filed but before a first office action is mailed in the RCE would need to comply with the time requirements of §§ 1.97(c) ("the second time period"), 1.97(d)(1) ("the third time period"), or 1.97(d)(2) ("the fourth time period"), whichever is applicable. If an RCE with IDS is filed after a Notice of Allowance is received but before payment of the issue fee, during "the third time period", the proposed rules would require applicants to make the certification in 1.97(e)(1) (that each reference was first cited in a foreign counterpart not more than 3 months prior to the filing of the IDS) or (e)(2) (that no reference was cited in a foreign counterpart and to the knowledge of the person signing the certification after reasonable inquiry, no information contained in the IDS was known to a § 1.56 individual more than 3 months prior to the filing of the IDS).

The proposed rules can create a situation where an applicant may not be able to meet its duty of candor under Rule 56. For example, if a notice of allowance is received and an applicant performs, or is requested by outside counsel, to perform one last review of his files prior to payment of the issue fee, and this final review reveals a document that was inadvertently not submitted earlier in prosecution, but was known to the applicant for more than 3 months, applicant would be precluded from having this document considered by the examiner because applicant could not make the certification under 1.97(e)(1) or (e)(2). With the Office's focus on ensuring that only high quality patents issue, it seems that the Office should not adopt rules that will preclude an applicant from submitting art that is material to patentability.

As the proposed rules allow applicants who are able to or elect to make the certifications under 1.97(e)(1) or (e)(2) to submit references after receipt of a Notice of Allowance but before or with payment of the issue fee (proposed § 1.97(d)(1)) or after payment of the issue fee (§ 1.97(d)(2)), GSK believes that the filing of an RCE, with the

requisite payment of the RCE fee, should provide an option to applicants who cannot or for whatever reasons elect not to make the certifications under 1.97(e)(1) or (e)(2).

Accordingly, GSK suggests that the proposed rules be revised to indicate that any IDS filed with an RCE or after an RCE is filed but before a first office action is mailed in the RCE would be considered as filed during the second time period (§ 1.97(c)) and would therefore need to comply with the additional disclosure requirements of § 1.98(a)(ii).

5. Revise requirements for providing an explanation under § 1.98(a)(3)(iv)

Under proposed § 1.98(a)(3)(iv), an explanation must include an identification of specific features that caused the document to be cited, an identification of relevant portions of the document where the specific features can be found, and a correlation of the specific feature to corresponding specific claim language. GSK believes that the identification and correlation requirement goes too far for at least the following reasons:

A. Foreign search reports do not include such a correlation, but are deemed to meet the explanation requirement

Under proposed § 1.98(a)(3)(viii)(A) and (B), submission of a foreign search report satisfies the explanation requirement of § 1.98(a)(3)(iv); however, foreign search reports do not typically include the type of identification required under § 1.98(a)(3)(iv). Furthermore, foreign search reports do not typically include the correlation required under § 1.98(a)(3)(iv). Instead, these search reports typically indicate a specific portion of the reference (e.g., page 5, lines 15-25) that makes the reference pertinent and the claims for which the identified disclosure in the cited reference is relevant. The search reports do not typically include an identification of specific features that caused the document to be cited, nor do they include a correlation of the specific feature to corresponding specific claim language.

GSK believes that an identification of the pertinent portion of the reference and an indication of the claims for which the pertinent portion is relevant would be more than adequate to meet the Office's goal of reducing the burden on the examiner. When the identified relevant claims are viewed in the context of the pertinent portion of the reference, the examiner can readily ascertain the pertinence of the cited reference to the claimed invention.

B. The proposed identification and correlation requirements exceed the Patent Office's statutory authority by, in essence, requiring applicant to examine his own claims

The Office derives its rulemaking authority from 35 U.S.C. § 2, which states, in pertinent part, that "The Office . . . may establish regulations, not inconsistent with law . . . ." (Emphasis added). Under U.S. patent law, it is clear that the Office has the duty to examine claims. 35 U.S.C. § 131 states that "The director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor." 37 CFR 1.104 describes some aspects of the duty of examination required of the patent office under the heading "Nature of Examination." For example, 37 CFR 1.104 states that:

> In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

By imposing the identification and correlation requirements of § 1.98(a)(3)(iv), the Office is, in essence, outsourcing a portion of the examination process to the applicant. In view of the penchant of various examiners to overlook the motivation to combine requirement of proving a prima facie case of nonobviousness, it is within the realm of possibility that a first office action could merely be a collection of applicant's explanations that provide all of the recited elements of a particular claim.

C. The proposed correlation requirement exceeds the Patent Office's statutory authority by improperly shifting the burden of proving patentability to the applicant

The Office derives its rulemaking authority from 35 U.S.C. § 2, which states, in pertinent part, that "The Office . . . may establish regulations, not inconsistent with law . . . ." (Emphasis added). The Office has the burden of proving that a claim is unpatentable. See, e.g., 35 U.S.C. § 102 "Conditions for patentability; novelty and loss of right to patent" stating that "A person shall be entitled to a patent unless . . . ." The proposed correlation requirement improperly shifts the burden to applicant to either admit that a claim recitation is taught in a prior art reference or distinguish a claim recitation from that which is taught in a prior art reference without that reference ever having been cited against the claims of the application. In so doing, the correlation requirement improperly shifts the burden of proving patentability to the applicant.

6. Documents considered in a parent application should not count against the document limit when cited in a continuing application for the purpose of having the documents appear on the face of the continuing patent

Under M.P.E.P. § 609.02(A)(2), the examiner will consider information which has been considered by the Office in a parent application when examining (A) a continuation application filed under 37 CFR 1.53(b), (B) a divisional application filed under 37 CFR 1.53(b), or (C) a continuation-in-part application filed under 37 CFR 1.53(b). A listing of the information need not be resubmitted in the continuing application unless the applicant desires the information to be printed on the patent.

Under the proposed rules, for continuing applications, documents of a compliant IDS in the prior application, which are required under M.P.E.P. § 609.02(A)(2) to be reviewed by the examiner in the continuing application, would not be considered as part of the cumulative total in the continuing application unless they are resubmitted in the continuing application (so that they will appear on the face of the patent that issues from the continuing application).

If the examiner is required to review the documents cited in the prior application and presumably is already familiar with the documents cited in the prior application, and the documents cited in the prior application are not automatically counted against the

cumulative total of the continuing application, it seems that applicant should be able to cite the documents from the prior application in an IDS in the continuing application, so that they will appear on the face of the patent, without the documents from the prior application counting against the cumulative total in the continuing application.

GSK suggests that the proposed rules (e.g., § 1.98(a)(3)(C)) be revised to indicate that documents of a compliant IDS in a prior application, which are required under M.P.E.P.§ 609.02(A)(2) to be reviewed by the examiner in the continuing application, would not be considered as part of the cumulative total in the continuing application if they are resubmitted in the continuing application during "the first time period".

7. Documents cited from prosecution of related application should not count against the document limit

Under certain scenarios, applicants may have the duty to cite one or more office actions from a patent application pending before the Office in an IDS of a co-pending application. In areas where applicants have a number of closely related co-pending applications, the burden on applicant to cite such prosecution history documents could cause the applicant to reach the twenty document limit of proposed rule 1.98(a)(3)(i)(C) in short order. Moreover, such documents could appear at any time during prosecution of the application.

GSK suggests that the proposed rules be revised to include an additional exception under § 1.98(a)(viii) that compliance with paragraphs (a)(3)(iv), (a)(3)(v), and (a)(3)(vi) of § 1.98 are not required for the citation of prosecution history documents, such as office actions, from co-pending applications and/or co-owned patents or applications.

8. Exclude documents exempt from additional disclosure requirements under § 1.98(a)(3)(viii) from the calculation under § 1.98(a)(3)(i)(C) of the total number of documents submitted during the first time period

Under proposed rule § 1.98(a)(3)(viii), certain classes of documents are exempt from the additional disclosure requirements. However, no provision is made for removing these excepted documents from the calculation of the number of documents submitted, calculated cumulatively, during the first time period, which triggers the imposition of the explanation requirement under § 1.98(a)(3)(i)(C).

A situation could occur where ten (10) documents that fall under one of the exceptions of § 1.98(a)(3)(viii) are submitted during the first time period, and applicant also submits eleven (11) documents that do not fall under the exceptions of § 1.98(a)(3)(viii) ("the nonexempt documents") during the first time period. The total number of documents submitted during the first time period would be twenty-one (21), thereby triggering the explanation requirement under § 1.98(a)(3)(i)(C) for all of the nonexempt documents, even though the total of the nonexempt documents is well below the twenty document threshold of § 1.98(a)(3)(i)(C).

GSK suggests that the proposed rules be revised to indicate in § 1.98(a)(3)(i)(C) that documents which are exempt from the explanation requirement by operation of §

1.98(a)(3)(viii) do not count in the calculation of total documents submitted under § 1.98(a)(3)(i)(C).

9. Clarify translation requirement under § 1.98(a)(3)(xi)

A. It is unclear from proposed rule 1.98(a)(3)(xi) whether a translation is required for a foreign language document that is cited in an IDS, where the search report is submitted with the document. For example, if a foreign language document is cited on the International Search Report, and the ISR is submitted with the IDS, does applicant have to provide a translation of the foreign language document.

B. Under proposed rule 1.98(a)(3)(xi), a copy of a translation must be submitted where a translation is within the possession, custody, or control of, or readily available to, any individual listed in § 1.56(c). It is unclear what is meant by the language "readily available to". For example, if the applicant has an in-house translation service for the language of the foreign language reference, is a translation deemed to be "readily available to" that applicant? As another example, if a translation can be obtained from a commercial translation service with minimal effort (e.g., placing a phone call, sending an e-mail, etc.) on the part of applicant, is a translation deemed to be "readily available to" that applicant? If the answer to the latter question is yes, then is the translation deemed to be "readily available to" the applicant regardless of the cost of obtaining the translation? If not, then what is the cost threshold at which a translation is no longer "readily available to" the applicant?

10. In view of the Office's proposed changes to claim examination practice, it is unclear whether an explanation is required for references that describe features in non-designated claims

Under the proposed changes to examination practice described in "Changes to Practice for the Examination of Claims in Patent Applications" 71 Fed. Reg. 61 (January 3, 2006) ("the proposed examination rules"), Applicants would be required to designate claims for examination. It is unclear from the proposed changes to IDS requirements whether applicants would be required to provide an explanation for features that appear in non-designated claims. If the proposed examination rules are adopted, it would seem that applicants should not have to submit an explanation for any feature that only appears in non-designated claims, as these claims are not examined by the Office for prior art purposes.

If the proposed examination rules are adopted, GSK suggests that proposed rule 1.98(a)(3) be revised to indicate that no explanation is required for any feature that only appears in a non-designated claim.

If the proposed examination rules are adopted in conjunction with the proposed changes to IDS requirements, GSK also suggests that § 1.56(a) be amended to clarify that the duty to disclose information only exists with respect to each claim that is both pending and designated, and that the duty to disclose information is extinguished if the claim is cancelled, withdrawn from consideration, or un-designated, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled, withdrawn from consideration, or un-designated need not be submitted if the information is not material to the patentability of any designated claim remaining under

consideration in the application. There is no duty to submit information which is not material to the patentability of any existing designated claim.

11. Clarify how the rules apply to reissue applications

It is not clear from the proposed rules how the rules would apply to reissue applications. For example, would an IDS submitted in a newly filed reissue application be in the "first time period" of § 1.97(b)?

GSK suggest that § 1.97 be revised to clarify how the rules apply to reissue applications.

12. Clarify non-retroactivity of the rules

It is not clear from the proposed rules whether the rules will be applied retroactively to any IDSs already submitted in applications that are pending as of the date that the proposed rules are adopted. In other words, it is not clear from the rules whether applicants will have a duty to provide the additional disclosure required by the new rules retroactively for IDSs already on file in pending applications as of the date that the proposed rules are adopted.

GSK suggests that the rules not be applied retroactively to any IDSs submitted prior to the date that the proposed rules are adopted, but instead be applied only to any IDS submitted on or after the date that the proposed rules are implemented. GSK also suggests that the Patent Office follow its standard practice of publishing the final rules at least thirty (30) days prior to the date on which the rules will be implemented.

Conclusion

GSK appreciates the opportunity to provide comments on the proposed rules.

Sincerely,

//s//

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline