-----Original Message-----
**From:** mike.m.strickland@gsk.com [mailto:mike.m.strickland@gsk.com]
**Sent:** Tuesday, May 02, 2006 4:21 PM
**To:** AB93Comments
**Subject:** GSK Comments on Continuing Application Practice

Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Mr. Clarke,

Attached are the comments of GlaxoSmithKline on the proposed rules changes to “Practice for Continuing Applications, RCE Practice, and Applications Containing Patentably Indistinct Claims.”

We appreciate the opportunity to offer our comments and would greatly appreciate confirmation that our comments have been received by the U.S Patent and Trademark Office.

Thank you.

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline

**Comments on Proposed Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims**

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: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner
for Patent Examination Policy

Comments on Proposed Rules: "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48 (January 3, 2006)

Dear Under Secretary Dudas:

In response to the Proposed Rulemaking published January 3, 2006, at Federal Register, Vol. 71, No. 1, p. 49-61, GlaxoSmithKline ("GSK") submits the following comments. Separate comments are submitted concurrently herewith directed to the related claim examination proposed rulemaking.

***Executive Summary:***

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. Through attendance at one of the many town hall meetings recently held by the Patent Office to further inform the public of the crisis facing the Patent Office and the need for patent reform, GSK has gained insights into the difficulties facing the Patent Office as it tries to cope with an ever increasing backlog of newly filed applications in the midst of a very tight job market for skilled workers to fill the growing ranks of the corps of examiners.

While GSK appreciates the position in which the Patent Office currently finds itself, GSK must oppose the proposed rulemaking because: (1) the Patent Office lacks authority to implement the proposed rulemaking; and (2) even if the Patent Office were to have authority, the proposed rulemaking will not work to meet the stated goals of the Patent Office of reducing workload and improving quality of examination. If the Patent Office decides to enact the proposed rules despite the lack of authority to do so, GSK requests consideration of alternatives, such as those discussed below. The proposal of

alternatives 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 even that GSK views the alternatives as rendering the proposed rules acceptable. GSK reserves the right to challenge any final rules through the appropriate legal channels.

At a minimum, GSK submits that the following points should be considered when revising the proposed rulemaking: (1) clarify sufficient showing for additional continuation/RCE; (2) provide a non-limiting list of reasons allowed for filing additional continuations or RCEs; (3) revise standard for obtaining additional continuations/RCEs; (4) draw a distinction between RCEs and continuations; (5) do not make the proposed rules retroactive; (6) allow divisional applications to claim priority to parent; (7) consider allowing for deferred examination; (8) clarify what is meant by language of proposed 1.78(f)(1); and (9) clarify what is meant by "substantial overlapping disclosure" in proposed 1.78(f)(2).

As the Patent Office has been most solicitous of comments regarding ways to improve the proposed rules rather than comments attacking the rules as unworkable, the body of these comments is organized to focus first on proposed alternatives, followed by an explanation of the reasons that the Patent Office lacks authority to enact the proposed rules as well as reasons that the proposed rules will not be effective to meet the stated goals of the Patent Office.

***Proposed Alternatives or Revisions to the Proposed Rulemaking:***

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

1. Clarify Sufficient Showing for Additional Continuation/RCE

It has been proposed that 37 CFR § 1.114 be amended to add the following paragraph:

> "(f) An applicant may not file more than a single request for continued examination under this section in any application. . .unless the request also includes...a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application."

Applicants often file continuations in order to comply with formal statutory requirements or to fight for claims they believe they are entitled to but which examiners refuse to grant. These Applicants are trying in good faith to obtain coverage they believe they are entitled to under the patent system.

The proposed rules provide that a continuation application or request for continued prosecution may be filed to obtain consideration of an amendment, argument, or evidence that "could not" have been submitted during prosecution of the prior filed application. In the absence of greater specificity in the rules, whether or not an amendment, argument, or evidence "could not" have been submitted would be a highly subjective determination on which reasonable people could differ by a wide degree. One technology center within the PTO might reasonably determine that an explanation by an examiner of a previous rejection requires a response that could not have been

presented earlier. Another technology center might reasonably determine that only a completely new rejection would require a response that could not have been presented earlier. In such a circumstance, one competitor in an industry might easily obtain a continuation application leading to useful claims while another competitor gains useless claims in prematurely truncated prosecution. Such disparate results could irreversibly harm the competitor lacking claims. The Office needs to provide a clearer standard for permitting or denying a second or subsequent RCE or continuation application.

Applicants petition to obtain an additional RCE or continuation must provide a "showing to the satisfaction of the Director". Out of necessity, the Director will not evaluate all such petitions and numerous other officials of the Office will be called upon to do so. This gives rise to the likelihood of disparate standards being in effect in different technology centers, and even within them. Such disparate standards would irreversibly prejudice applicants to which a more rigorous standard was applied. For example, a first competitor might easily obtain an additional continuation application and refine their claims to carefully comply with the Patent Statute and protect their invention. A second competitor, held to a more rigorous standard, might be delayed in gaining protection due to the need for an appeal followed by additional prosecution. The second competitor lacked protection for their technology and was at a disadvantage in the market place compared to the first competitor. Such disparate results could irreversibly harm the competitor lacking claims. The Office needs to provide a clearer standard for permitting or denying a second or subsequent RCE or continuation application.

2. Provide a Non-Limiting List of Reasons Allowed for Filing Additional Continuation or RCE

One way of providing a clearer standard is to provide a non-limiting list of reasons that will be deemed a per se showing to the satisfaction of the Director or, alternatively, to provide a non-limiting list of reasons for which a petition for an additional continuation or RCE will not be required.

At The Fifth Annual Hot Topics in Intellectual Property Law Symposium, held at Duke Law School on February 17, 2006, John Whealan, Deputy General Counsel, Intellectual Property Law and Solicitor, United States Patent and Trademark Office, was asked what would satisfy the "showing to the satisfaction of the Director." He commented that the showing would be met if, for example, (1) the applicant was obtaining data to overcome a prima facie case of obviousness and it took longer than the pendency of the first continuation or RCE to obtain the necessary data, or (2) the Examiner cited a new reference in a final office action of the first continuation or RCE and the applicant had not yet had an opportunity to address the newly cited reference. Including these specific reasons for allowing additional continuations/RCEs in the proposed rules would be a step in the right direction, but we believe that it would not go far enough.

Additional reasons that should be listed as providing a showing sufficient to support an additional continuation or RCE filing would include:

(1) Filing of an Information Disclosure Statement (IDS) should be considered an allowed reason for filing an additional RCE where the applicant cannot make the certification required for submission of such art at the time of filing of the IDS. In light of current Rule 1.56 practice and inequitable conduct law, applicants are compelled to

submit art to avoid being second-guessed as to the materiality of such art, regardless of when the art comes to the applicants' attention or, more accurately, whenever it comes to the attention of their patent prosecutor. In the certain circumstances where a large number of individuals could fall within the scope of Section 1.56(c), it may be a practical impossibility to reliably certify under Section 1.97(e) that none of these individuals ever had prior knowledge of the art being submitted.

(2) Where the filing of the additional continuation may be needed to promote innovation in a particular industry. For example, in the pharmaceutical industry, an additional continuation may be needed to promote continued development of a pharmaceutical compound. Under 35 U.S.C. § 156, the term of a patent can only be extended once based on regulatory review for a product that has been subject to a regulatory review period before its commercial marketing or use. In certain situations, more than one continuation application may be needed to provide a business justification for continuing development of a pharmaceutical compound. For example, an original patent application could be filed with claims that cover a genus of pharmaceutically active compounds. After the filing of the patent application, research and development efforts may identify two or more compounds within the genus that show particularly high activity such that they are designated as lead and back-up compounds for treatment of a particular disease. Before the issuance of the patent covering the genus, a first continuation application may be filed directed to the lead and back-up species. It may be discovered that one of the back-up compounds is a lead compound for treatment of another disease. If this discovery comes prior to the issuance of the first continuation, it will likely be desirable to file a second continuation application directed to the new lead compound species, thus providing for one patent that provides species protection for a first marketed compound and a separate patent that provides species protection for a second marketed compound. It is necessary to have separate species patents because, as noted above, under 35 U.S.C. § 156, the term of a patent can only be extended once based on regulatory review for a product that has been subject to a regulatory review period before its commercial marketing or use. Thus the second continuation would be needed to allow for the patent term extension warranted by the regulatory delay in obtaining approval of the second marketed compound.

(3) An additional RCE may be needed in order to rebut an arguable prima facie case of obviousness when the applicant has made a strategic decision during prosecution to attempt first to rebut the prima facie case of obviousness, and only later attempts to overcome the prima facie case of obviousness by submitting data. For example, claims are rejected under 35 USC § 103. Applicant has a good faith belief that the Examiner's position is incorrect, and presents arguments to rebut the *prima facie* case. The Examiner is unconvinced and finally rejects the claims under 35 USC § 103. Although experiments could have been initiated when the rejection was first entered they were not, and now the case is at final rejection and the only way to overcome the rejection is by presenting comparative data to overcome the *prima facie* case. The Patent Office needs to make it clear that the need to generate data based on facts such as these would constitute a sufficient showing to allow an additional RCE.

(4) The proposed rules would restrict the ability of an applicant to take allowance and issue of claims and to pursue broader or additional claims in a continuation application. Issuing such a patent provides advantages for both applicant and the PTO. Therefore, a continuation should always be allowed if applicant accepts allowance and

issue of a patent and employs the continuation to pursue additional subject matter beyond the allowed and issued claims.

3. Consider Adopting a "Bona Fide Attempt" Standard

Another way of providing a clearer standard for filing a second or subsequent continuation or RCE is to reformulate the proposed standard of review from an inquiry into whether the amendment, argument, or evidence could have been submitted prior to the close of prosecution in the application to a determination as to whether the filing is a bona fide attempt to advance prosecution. This standard is already being employed by the Patent Office. For example, the Patent Office currently uses such a standard to evaluate responses to Office Actions. The use of a bona fide attempt standard of review would address each of the scenarios set forth in the immediately preceding subsection. Submission of an IDS, filing of a second or subsequent continuation in order to promote innovation in an industry, filing of an RCE to continue attempting to assert a lack of a prima facie case of obviousness or to submit evidence to rebut a prima facie case of obviousness after such attempts have not been fruitful, or filing a continuation in order to seek broader claims while allowing narrower claims to issue would all be bona fide attempts to advance prosecution.

4. Draw a Distinction between RCEs and Continuations

The proposed rules provide uniform treatment for requests for continued examination, continuation applications, and divisional applications. The proposed rules should be revised to account for the differences between these practices. For example, a RCE provides only additional examination. In contrast, a continuation application allows an applicant to take allowance and issue of claims and to pursue broader or additional claims. Issuing such a patent provides advantages for both applicant and the PTO. As such, a continuation application is not identical to an RCE. Therefore, filing an RCE should not preclude later filing of a continuation application, and vice versa.

5. Do Not Make the Proposed Rules Retroactive

To prevent arbitrary and random prejudice against certain applicants, the proposed rules should apply only to applications filed after the effective date of the rules and that claim priority to no earlier application.

A. In General

The proposed rules would restrict the ability of an inventor with an application pending on the effective date from pursuing additional RCEs, continuations, or divisionals. The inventor would have filed or prosecuted the application without anticipating that his or her options would be severely restricted, possibly as soon as in response to the next office action. In art units with a large backlog, this could affect applications filed long ago. Some pending applications may have been subject to no examination when these rules take effect. Other pending applications may have been subject to extensive prosecution and have many pending continuations and divisionals. The effect of the proposed rules would thus have widely varying impact on different applicants due to no fault of their own.

B. Retroactivity is Particularly Egregious for Divisional Applications

Under the proposed rules, divisional applications can only claim priority to one prior application. There are likely numerous applicants that have utilized the divisional filing strategy of filing a first divisional application during the pendency of the parent application, allowing the parent to issue, filing a second divisional application during the pendency of the first divisional application, allowing the first divisional application to issue, filing a third divisional application during the pendency of the second divisional application, etc. For these applicants, the retroactivity of the proposed rules is particularly egregious because it may result in a situation where the issued parent patent, or more likely the published parent application, is 102(b) prior art to the newly filed divisional application. For example, in the above scenario, if the rules are implemented while the second divisional application is pending and the applicant wishes to file a third divisional application, the third divisional application could only claim priority to the second divisional application, in which case the issued parent patent would likely be 102(b) prior art to the third divisional application. This result is simply untenable.

6. Allow Divisional Applications to Claim Priority to Parent

The Patent Office should allow divisional applications to claim priority back to an original restricted parent application through intervening applications, as with current practice. Allowing this practice to continue will avoid the egregious result outlined in 4(A) above and will avoid having the Patent Office inundated with a significant number of divisional applications that likely would not otherwise have been filed. In some art units, where multi-way restrictions are common under current practice, divisionals may be filed in series as described above, and additional information relevant to the desirability of filing of further applications may be obtained during pendency of the preceding application. As a result, later-filed divisional applications will no longer be of interest to the applicants in light of information that was not available during pendency of the original restricted application, and these later-filed applications would not be filed.

7. Consider Allowing for Deferred Examination

The PTO should consider the implementation of a deferred examination system as a practical way to reduce the application backlog at the PTO, provide greater value to PTO customers, and limit the issuance of multiple patents in certain situations. A deferred examination system, similar to the system successfully in effect for many years in Japan, would give an applicant the option of delaying examination for a period of years. This would reduce the number of applications being substantively handled by the office. Further, it would allow applicants time to determine whether a particular invention was economically viable prior to committing additional resources, and tapping the resources of the PTO, to undertake the process of substantive examination. This deferral option would also allow applicants to more fully investigate the state of the particular technology prior to substantive prosecution, and would increase the overall efficiency of the examination process.

It is expected that the pendency of all applications would drop if deferred examination were implemented, because substantive examination would typically not begin until after the deferral period (which would not count against pendency) had elapsed. In addition, a portion of applications filed could be expected to be abandoned by applicants during the deferral period, without the expenditure of PTO resources on

substantive examination, further reducing the burden on the PTO. A deferred examination system would be consistent with the public notice function of the patent system, because it would not affect existing pre-grant publication, which occurs at eighteen months from the first priority date in the great majority of cases. Adoption of a deferred examination system would reduce the application backlog at the PTO and improve the quality of the patent system, without unnecessary adverse effects on legitimate stakeholders. Deferred examination would also be a positive and useful step toward harmonization of the world's major national patent systems.

8. Clarify What is Meant by Language of Proposed 1.78(f)(1)

Proposed § 1.78(f)(1) states: "If a nonprovisional application has a filing date that is the same as or within two months of the filing date of one or more other pending or patented nonprovisional applications, taking into account any filing date for which a benefit is sought under title 35, United States Code . . . ." The Patent Office should clarify what is meant by the underlined language. For example, does this language mean that applicants are required not only to look at the specific filing dates of the applications in question, but also at any priority dates claimed in either application? If so, it may be impracticable to comply with this proposed rule.

9. Clarify What is Meant by "Substantial Overlapping Disclosure" in Proposed 1.78(f)(2)

Proposed § 1.78(f)(2) states that if the non-provisional application and pending non-provisional application or issued patent cited in § 1.78(f)(1) have the same filing date and contain "substantial overlapping disclosure," then a rebuttable presumption shall exist that at least one claim of the non-provisional application is not patentably distinct from at least one claim in a cited pending non-provisional application or patent. Applicant must either rebut the presumption by explaining how the claims are patentably distinct or file a terminal disclaimer.

It is unclear whether the term refers to the description in the specification, the claims, or both. If the phrase refers to the claims, examples should be provided by the Office as "substantial" is a relative term; in other words, how much overlap must there be to reach the "substantial" threshold. For example, consider two separate cases for completely different compounds (each is a single species case). As the chemistry section of each of these would be small, the backgrounds, biological data, formulation language, and other related sections could, by themselves, result in a finding of substantial overlapping disclosure, even though the inventions themselves (as defined by the claims) are in no way related.

GSK offers the foregoing comments to aid the Patent Office in the event the Office decides to adopt the proposed rules. Notwithstanding these comments, GSK submits that the Patent Office lacks the authority to adopt the proposed rules, and that, even if the Patent Office did have the authority to adopt the proposed rules, these rules would not aid the Patent Office in achieving its stated goals.

***The Patent Office Lacks Statutory Authority:***

1. The proposed limitations to the filing of continuation applications exceed the Patent Office's rulemaking authority

The Patent 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). As described below, it is clear that, under U.S. patent law, there are no statutory limits as to the number of continuing applications that can be filed. Accordingly, the Patent Office does not have the authority to adopt a rule that limits the number of continuing applications that can be filed.

It is clear from the language of the statute that there are no statutory limits as to the number of continuing applications that can be filed. 35 U.S.C. §120 states that "An application for patent for an invention. . . ***shall*** have the same effect, as to such invention, as though filed on the date of the prior application. . . ." Use of the word "shall" means that Congress intended the statute to represent the minimum requirements to obtain the benefit of the filing date of the prior application. An agency, like the PTO, may not promulgate a rule or regulation that adds a requirement that does not exist under the statute. 2 Am Jur 2d, §132, page 141. Likewise, a regulation that contravenes a statute is invalid. *See,* R & W Flammann GmbH v. U.S., 339 F.3d 1320 (Fed. Cir. 2003), *citing* United States v. Vogel Fertilizer Co., 455 U.S. 16 (1982). The Federal Circuit further has held that "[e]ven substantive rules cannot be promulgated that are contrary to statute. If the intent of Congress is clear, that is the end of the matter. . . ." Travelstead v. Derwinski, 976 F.2d 1244, 1250 (Fed. Cir. 1992), *citing* Chevron U.S.A. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

It is clear from the judicial interpretation of the statute that there are no statutory limits as to the number of continuing applications that can be filed. The C.C.P.A. has held that there is no statutory basis under 35 U.S.C. § 120 to limit the number of continuation applications allowed an applicant who otherwise complies with the requirements of 35 U.S.C. § 120. (*See In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968); *In re Bogese II*, 303 F.3d 1362 (Fed. Cir. 2002) (holding that the PTO's forfeiture of an applicant's rights to a patent due to unreasonable delay was not arbitrary does not alter the holding of *Henriksen*)).

It is even clear from recent Congressional actions that there are no statutory limits as to the number of continuing applications that can be filed. The Patent Reform Act of 2005, introduced in the House of Representatives last year, included a proposed new section 123 to the patent statutes that, if enacted, would have granted the Director a limited authority to adopt regulations that placed limitations on the filing of continuation applications. *See*, The Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 8 (2005). The language of the proposed § 123 is as follows:

> **Sec. 123. Limitations on continuation applications**
>
> The Director may by regulation limit the circumstances under which an application for patent, other than a divisional application that meets the requirements for filing under section 121, may be entitled to the benefit under section 120 of the filing date of a prior-filed application. No such

> regulation may deny applicants an adequate opportunity to obtain claims for any invention disclosed in an application for patent.

The Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 8 (2005). It is clear from this proposed language that Congress appreciates that the Director does not have the statutory authority under the existing patent laws to limit the number of continuing applications that an applicant can file, and that Congress would need to grant the Director this additional authority to enable the Director to promulgate such rules.

The Patent Office appears to acknowledge that it has no authority to place an absolute limit on the number of copending continuing applications originating from an original application, but asserts, "The Office does not attempt that here." Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 50 (January 3, 2006). While it is true that the Patent Office is not proposing a rule that would set a per se absolute limit on the number of continuing applications that could be filed, the proposed rules leave it to the Director's discretion as to whether a further continuing application can be filed. If the Director exercises his discretion in any way and disallows the filing of a further continuing application, at that point in time the Director will exceed his authority as described above by placing a limit on the number of continuing applications that can be filed.

As an example of a particular situation where the Director's exercise of his discretion will cause him to exceed his authority, officials from the Patent Office have commented publicly that the following would not satisfy the showing requirement for an additional continuation or RCE: (1) if the applicant does not know what his competitor is going to do and wants to keep an application pending in order to draft claims that are fully supported by the specification once the market develops; and (2) if the applicant does not yet know if he wants to invest in the product/needs more time to determine what the commercial embodiment of the product will be, and thus what claims will be needed to cover the commercial embodiment. These comments along with others made by officials of the Patent Office at various Town Hall meetings have made it apparent that one of the reasons for the proposed changes to continuation practice is to address the PTO's concern that, despite the 18-month publication of many U.S. patent applications, continuation practice is still being used for "submarine" patents which are stifling competition. If the Director were to refuse to allow the filing of an additional continuation or RCE for the reasons suggested above, the Director would clearly exceed his authority as the Patent Office is not a policy making agency and these reasons for not allowing additional continuations/RCEs are clearly reasons rooted in a public policy position that disfavors continuation applications. Accordingly, adopting the proposed rule changes will expose the Patent Office to lawsuits challenging the agency's authority to implement the rules, which will increase rather than decrease the burden on the Patent Office's resources.

For at least the foregoing reasons, the Patent Office does not have the authority to adopt a rule that limits the number of continuing applications that can be filed.

2. The proposed limitations to the filing of divisional applications exceed the Patent Office's rulemaking authority

35 U.S.C. §121 states that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it ***shall*** be entitled to the benefit of the filing date of the original application." As described above, the Patent Office has no authority to limit the number of continuation applications that comply with the statutory requirements of 35 U.S.C. § 120. Accordingly, the Patent Office also does not have the authority to adopt a rule that limits the number of applications to which a divisional application can claim priority.

3. The proposed limitations to the filing of Requests for Continued Examination exceed the Patent Office's rulemaking authority

35 U.S.C. § 132 (b) states, "[t]he Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title." (Emphasis added). If Congress had intended to grant the Director the authority to use his discretion to limit the number of continued examinations that an applicant could request, Congress would have done so explicitly. Congress has not done so, and accordingly, the Patent Office does not have the authority to adopt a rule that limits the number of Requests for Continued Examination that an applicant can file.

4. The proposed rule under which the Patent Office will presume claims to be patentably indistinct on the basis of overlapping subject matter in a concurrently filed application exceed the Patent Office's rulemaking authority

The Patent Office has the statutory burden to prove that a claimed invention is not patentable. 35 U.S.C. §102 states that a ***person shall be entitled to a patent unless***. . . "

The Patent Office does not have the authority to shift the burden to applicant to prove the patentability of a claimed invention absent evidence that establishes a *prima facie* case that the claimed invention is not patentable. 35 U.S.C. §103. The mere existence of overlapping subject matter in the disclosure of co-pending applications does not establish a *prima facie* case that the claimed invention is not patentable.

Statutory double patenting can only occur when the subject matter claimed in different applications or in an application and an issued patent is the same. Obviousness-type double patenting requires that the claimed invention be obvious in view of the claims of the co-owned application or patent, not in view of the disclosure of the co-owned application or patent. Thus, mere overlapping subject matter in the disclosure does not establish a *prima facie* case of unpatentability. In fact, any similarity of disclosures, substantial or otherwise, is irrelevant to a determination of statutory or obviousness-type double patenting.

For at least the foregoing reasons, the proposed rule under which the Patent Office will presume claims to be patentably indistinct on the basis of overlapping subject matter in a concurrently filed application exceeds the Patent Office's rulemaking authority.

***The Patent Office Goals Will Not Be Met:***

Even if the Patent Office were to have authority to limit continuing application practice as proposed, such a change would not address the Patent Office workload or quality of examination goals. As an initial matter, based on data presented by the Patent Office at various town hall meetings, only a limited number of cases would be affected by the proposed rulemaking. While this data may have been presented in anticipation of the outcry of objections from affected parties, it also follows that the potential benefit to the Patent Office is likewise, at best, very limited.

An unintended effect of the proposed rulemaking is that the number of applications filed will likely increase, not decrease, in light of the limitation of claiming priority in a divisional application to only a single application. In other words, numerous divisional applications may be filed during pendency of the restricted parent application that might otherwise never have been filed. In fact, the proposed rule regarding claims of priority in divisional filings appears to have no basis in reducing the number of pending applications as stated in the proposed rulemaking. Instead, this proposed rule appears to be rooted in the Patent Office's publicly stated disdain for "submarine" patents, and seems to be implemented as a way of ensuring that the disclosure in a patent application is either claimed in a patent or dedicated to the public within approximately 6-8 years of the initial filing date (roughly the time needed to issue a patent in a parent application and one continuation or divisional application). As noted above, the Patent Office is not a policy-making agency, and thus it is not within their purview to regulate the length of time that a patent disclosure is available for claiming.

In addition to increased filings due to the limitations on divisional practice, applicants will be more likely to traverse restriction requirements. This will significantly add to the Patent Office's workload.

In limiting the ability of applicants to resolve issues with an Examiner in a pending application, additional unintended consequences may burden the Patent Office. For example, the Patent Office notes the success of the Pre-appeal brief panel review procedure under current practice. However, under the proposed rulemaking, the number of petitions for such panel review is likely to increase dramatically. In other words, any savings in Patent Office resources provided by reducing the opportunity for continued prosecution before an Examiner will likely be offset by an increased burden in panel review, involving three examiners in each instance. This increased workload may, in turn, reduce the quality of those panel reviews, resulting in an increased number of appeals that proceed to the Board of Patent Appeals and Interferences (BPAI) as a result of oversights by the reviewing panels. Applicants may also be more likely to pursue their appeals beyond the BPAI to the federal courts. As a result, the Patent Office may be inadvertently shifting the backlog from the corps of examiners to the BPAI and the Solicitor's Office. The Patent Office has publicly expressed how difficult it is to hire and train qualified examiners to handle the growing application backlog; however, it is hard to believe that the hiring and training of administrative law judges and lawyers to

expand the ranks of the BPAI and the Solicitor's Office would present a lesser burden for the Patent Office.

For at least the reasons discussed above, GSK believes the proposed rulemaking will fail to reduce Patent Office workload or improve the quality of examinations.

***Conclusion***

GSK understands the need for a strong and effective patent system that efficiently produces patents of the highest quality and appreciates the efforts undertaken by the Patent Office to attempt to improve the patent system. However, for at least the foregoing reasons, GSK submits that this proposed rulemaking will not result in the desired improvements.

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

Sincerely,

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline