From: Mike Strickland
Sent: Friday, August 20, 2010 3:14 PM
To: 3-tracks comments
Subject: GlaxoSmithKline Comments on Enhanced Examination Timing Control Initiative

Dear Sir:

Attached please find comments on the enhanced examination timing control initiative submitted on behalf of GlaxoSmithKline.

Best regards,

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline

**Comments on Enhanced Examination**
**Timing Control Initiative**

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

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

Attn: Robert A. Clarke

Comments on Enhanced Examination Timing Control Initiative
75 Fed. Reg. 31764 (June 4, 2010)

Dear Under Secretary Kappos:

In response to the Request for Comments on the Enhanced Examination Timing Control Inititative published June 4, 2010, at Federal Register, Vol. 75, No. 107, p. 31763-31768, GlaxoSmithKline ("GSK") submits the following comments.

***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. GSK is encouraged that the Patent Office is considering ways to provide patent applicants with the opportunity to control the timing of patent examination. As highlighted by the Patent Office, such procedures will benefit applicants and may result in reducing the backlog of patent applications awaiting examination.

GSK provides comments on some of the questions posed by the Patent Office in the order in which they are presented in the Notice.

***Comments on the Initiative***

1. **Should the USPTO proceed with any efforts to enhance applicant control of the timing of examination?**

   GSK believes that the USPTO should proceed with such efforts.

2. **Are the three proposed tracks the most important tracks for innovators?**

   GSK believes that the three tracks (prioritized examination, traditional timing, and an applicant-controlled up to 30-month queue prior to docketing) are logical examination tracks that are likely to be important for innovators.

3. **Should more than three tracks be provided?**

   GSK believes that three tracks should be sufficient.

4. **Should there be a single queue for examination of all applications accelerated or prioritized?**

   GSK believes that, for the sake of efficient administration, a single queue makes sense.

5. **Should an applicant who requested prioritized examination of an application prior to filing an RCE be required to request prioritized examination and pay the required fee again on filing of an RCE?**

   If RCEs are to be placed in a queue with continuing applications as has been suggested by the Patent Office, then GSK believes that a new request for prioritized examination with an accompanying fee may be justified. However, if RCEs continue to remain in the queue of normal prosecution of the application (e.g., as would any response during the prosecution of the application), GSK believes that such a requirement and fee would not be justified.

6. **Should prioritized examination be available at any time during examination or appeal to the BPAI?**

   GSK believes that prioritized examination should be available at any time during examination or appeal. Filing of a request with payment of the required fee at the appeal stage could provide appellants who are most desirous of resolution of their appeal with a way to seek an earlier review.

   The Patent Office must be aware, however, that injustices could arise. For example, assume that, upon initiation of the program, an applicant has had an application up on appeal for three years and is fully expecting resolution within the next year. The applicant elects not to request prioritized examination because resolution is relatively imminent. Many other applicants who are just beginning the appeal process decide to take advantage of the procedure, however, and as a result, the expected time for resolution of the first filer goes from one year to two to three

years. This does not seem to be a fair outcome as the first filer would then be forced to file a petition with requisite fee to obtain an outcome that would have otherwise been available without the payment of an additional fee. The Patent Office could address these situations by implementing a transition period during which time applications for which examination/resolution of appeal is imminent will remain at the front of the queue with prioritized applications being placed immediately behind these applications in the queue.

7. **Should the number of claims permitted in a prioritized application be limited?**

   GSK believes that the number of claims should not be limited, but instead there should be an additional prioritization surcharge for each excess independent and dependent claim.

8. **Should other requirements for use of the prioritized track be considered, such as limiting the use of extensions of time?**

   GSK believes that the Patent Office could consider other requirements that help promote compact prosecution. As for limiting the use of extensions of time, GSK believes that the Patent Office should consider setting shorter shortened-statutory times for responses to office actions (e.g., one month instead of three), with the applicant having the ability to pay for up to a five-month extension of time.

9. **Should prioritized applications be published as patent application publications shortly after the request for prioritization is granted?**

   GSK does not believe that this should be done automatically. There should be some circumstances in which the patent grants before the application would have published, saving the Patent Office the resources required to publish both the application and the patent. The Patent Office may wish to include a checkbox on the request for prioritized examination form to facilitate the applicant's decision to elect this option.

10. **Should the USPTO provide an applicant-controlled up to 30-month queue prior to docketing for examination as an option for non-continuing applications?**

    GSK believes that the USPTO should provide this option. There may be some applicants who elect to delay docketing and examination to determine if their invention is financially viable.

11. **Should eighteen-month patent application be required for any application in which the 30-month queue is requested?**

As any grant of the patent will be delayed by up to 2 ½ years, GSK believes that there should be such a requirement so that the public is put on notice of the pending application.

12. **Should the patent term adjustment (PTA) offset applied to applicant-requested delay be limited to the delay beyond the aggregate USPTO pendency to a first Office action on the merits?**

For applications in Track III, GSK believes that there should be an offset. However, as the pendency to a first Office action varies from art unit to art unit, GSK believes that the pendency to a first Office action on the merits for the particular art unit in which the application will be examined should be used to calculate the offset rather than an aggregate offset across all art units. The timing of the calculation of the offset may also be an important factor to consider. GSK believes that the offset should be determined as of the effective U.S. filing date of the application.

13. **Should the USPTO suspend prosecution of non-continuing, non-USPTO first-filed applications to await submission of the search report and first action on the merits by the foreign office and reply in USPTO format?**

GSK believes that the Patent Office should not treat non-USPTO first-filed applications differently from USPTO first-filed applications. If the Patent Office does choose to suspend prosecution in non-USPTO first-filed applications as suggested in this question 13, GSK believes that the Patent Office needs to make a distinction between: (1) U.S. applications filed under 35 U.S.C. 111(a) that claim priority directly to a foreign-filed application; and (2) U.S. national stage applications filed under 35 U.S.C. § 371 that stem from a PCT application which claims priority to a foreign-filed application.

In the case of applications filed under 371, GSK believes that prosecution should *not* be suspended because there is a high likelihood that the first-filed foreign application served as a priority application that was abandoned in favor of the PCT application, which can then be used to enter the country of first filing during the national stage.

If the Patent Office decides not to make a distinction between the two types of scenarios described above, GSK believes that the Patent Office should make it easy for the applicant filing a 371 application to indicate that the first-filed foreign application is not being pursued by adding an appropriate check box on the national stage filing form, for example.

14. **Should the PTA accrued during the suspension of prosecution to await the foreign action and reply be offset? If so, should that offset be linked to the period beyond average current backlogs to first Office action on the merits in the traditional queue?**

GSK believes that offsetting PTA accrued during the suspension of prosecution to await foreign prosecution and reply as described in the Request for Comments would exceed the Patent Office's statutory authority. With respect to PTA accrual, the statute clearly states:

> Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-
>
> (i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-
>
> the date on which an application was filed under section 111(a) of this title; or
>
> the date on which an international application fulfilled the requirements of section 371 of this title.

35 U.S.C. § 154(b)(1)(A)(i). Also, with respect to B-delay, the statute is equally clear in stating:

> Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-
>
> (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
>
> (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or
>
> (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph

(3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B).

Patent term adjustment reduction is governed by the language of 35 U.S.C.§ 154(b)(2)(C), which clearly states:

> (i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
>
> (ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.
>
> (iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Thus, the Patent Office is authorized to reduce PTA "by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." If the Patent Office were to implement regulations that delayed examination of an application claiming priority to a foreign filed application until after receipt of the foreign office action and reply, it would be improper to state that the applicant failed to engage in reasonable efforts to conclude prosecution of the application for any period of time that exceeded the average current backlog to first Office action on the merits in the traditional queue, which is, in essence, what the Patent Office is suggesting by the proposed offset.

Rather than adopt a one-size-fits-all patent term adjustment offset, it appears that the Patent Office would need to delve into the specifics of the foreign prosecution to determine if the applicant had "failed to engage in reasonable efforts" to advance the foreign prosecution to a first office action. As patent procedures vary from country to country, this inquiry will not be a trivial one and would require the Patent Office to adopt a far more nuanced approach that takes

into account the particular facts of each case in order to derive regulations that would have a decent chance of withstanding judicial scrutiny.

While GSK believes that the Patent Office does not have the statutory authority to implement offset as described in the Request for Comments, should the Patent Office decide to proceed with implementation of offset, GSK believes that as the pendency to a first Office action varies from art unit to art unit, the pendency to a first Office action on the merits for the particular art unit in which the application will be examined should be used to calculate the offset rather than an aggregate offset across all art units. The timing of the calculation of the offset may also be an important factor to consider. GSK believes that the offset should be determined as of the effective U.S. filing date of the application.

15. **Should a reply to the office of first filing office action, filed in the counterpart application filed in the USPTO filed in the USPTO as if it were a reply to a USPTO Office action, be required prior to USPTO examination of the counterpart application?**

GSK believes that it may make sense to require a reply to the foreign office action prior to USPTO examination. GSK believes that it may pose an undue burden on applicants, however, to require that the reply be provided in USPTO format. GSK believes that there should only be a requirement for applicant to submit an English translation of both the office action and the reply. If the applicant elects to make any claim amendments in conjunction with supplying the required documents to the Patent Office, the claim amendments would need to be submitted as a preliminary amendment accompanying the submission.

16. **Should the requirement to delay USPTO examination pending the provision of a copy of the search report, first action from the office of first filing and an appropriate reply to the office of first filing be limited to where the office of first filing has qualified as an International Searching Authority?**

GSK believes that limiting the application of the requirement to situations where the office of first filing has qualified as an International Searching Authority would not be fair to applicants for which one of the applicable countries is routinely the country of first-filing.

17. **Should the requirement to provide a copy of the search report, first action from the office of first filing and an appropriate reply to the first action in the USPTO application be limited to where the USPTO application will be published as a patent application publication?**

Under 35 U.S.C. § 122, if an applicant makes a request upon filing, certifying that the invention disclosed in the application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing, the application shall not be published. GSK believes that limiting the application of the requirement in such a way would not be fair to applicants for which their routine office of first filing is an office that requires publication.

18. **Should there be a concern that many applicants that currently file first in another office would file first at the USPTO to avoid the delay and requirements proposed by this notice? How often would this occur?**

Many applicants outside the U.S. may not be able to afford the added expense of altering their filing strategy to file first in the United States, but is seems inevitable that some applicants will choose to adopt this strategy. GSK does not have an opinion as to how often this would occur.

19. **How often do applicants abandon foreign filed applications prior to an action on the merits in the foreign filed application when the foreign filed application is relied upon for foreign priority in a U.S. application? Would applicants expect to increase that number if the three track proposal is adopted?**

As GSK files most, if not all, of its applications under the Patent Cooperation Treaty, GSK routinely abandons first-filed foreign applications that are relied upon for foreign priority. GSK would likely not increase that number based on adoption of the three track proposal.

20. **Should the national stage of an international application that designated more than the United States be treated as a USPTO first-filed application, or should it be treated as a continuing application?**

GSK believes that the national stage application should be treated as a first-filed application.

As GSK does not have an opinion on supplemental searches by IPGOs, GSK has elected not provide answers to questions 21-33.

***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 improve the patent system. GSK appreciates the opportunity to provide comments on the proposed enhanced examination timing control initiative.

Sincerely,

J. Michael Strickland
Senior Patent Counsel
GlaxoSmithKline