From:
Sent: Monday, March 08, 2010 3:37 PM
To: patent_quality_comments
Subject: Comments on Enhancement in the Quality of Patents - submitted by GlaxoSmithKline
Importance: High

To: United States Patent and Trademark Office,

I attach comments on behalf of GlaxoSmithKline in response to its Request for Comments on Enhancement in the Quality of Patents (FR/74, 235).

Respectfully yours,

Lorraine B. Ling
Vice President, Global Patents
GlaxoSmithKline

March 8, 2010

By email: patent_quality_comments@uspto.gov

Response to Request from USPTO for Comments on

Enhancement in the Quality of Patents

By:

GlaxoSmithKline

Introduction

GlaxoSmithKline ("GSK") appreciates the opportunity to submit its suggestions to the Patent and Trademark Office ("PTO") in response to the PTO's Request for Comments on Enhancement in the Quality of Patents (FR/Vol. 74, No. 235).

GSK is a major global pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer. Our business comprises three types of products: prescription medicines, vaccines, and consumer healthcare. We employ over 99,000 people in 114 countries. The cost of drug research and development (R&D) has increased from approximately $230 million per drug in the early 1980's to $1.2 billion today, with R&D currently requiring about 10-15 years per drug[1]. To protect this investment, GSK currently has over 1,500 pending US patent applications and over 2,000 granted US patents. In 2009 alone, GSK filed over 400 priority patent applications.

As a key industry stakeholder in the U.S. patent system, GSK wants to actively partner with the USPTO to create the model patent office of the future - one that transforms the relationship between the Office and the Applicant to an efficient and effective collaboration that produces a high quality product. We understand that both the PTO and the users carry some responsibility to achieve this objective, and that both the PTO and the users will greatly benefit if we succeed together.

As a global company, GSK is also keenly aware that the strength of a national economy is directly linked to whether the legal framework of the country promotes and protects innovation. During the current period of global economic challenges, it is important to reinvigorate the economy by issuing more patents of quality that can be used to attract capital and build new businesses and products.

GSK strongly commends the PTO for reaching out to the community for its ideas on how to go forward in a manner that does not include unduly burdensome and perhaps even objectionable regulations. The PTO has requested comments focusing on items relating to the quality of the examination process. These include, but are not limited to, identifying and analyzing the best prior art, submitting a comprehensive initial application, providing a

[1] *J.A. DiMasi et al. / Journal of Health Economics 22 (2003) 151–185*

comprehensive first Office Action on merits, with a clear explanation of all issues, submitting a comprehensive and clear response to Office Actions on the merits and ensuring the proper use of interview (FR/Vol. 74, No. 235).

Summary of Recommendations

In response to the PTO's request, GSK offers several suggestions regarding quality enhancement.

1. Economics is a key driver for patent quality. We are in favor of fee setting authority for the USPTO and against diversion of PTO income to other areas of the federal government. GSK also recommends that the fee schedule be reconsidered to provide incentives for desired user conduct. A new fee schedule should include a sliding scale cost to review references and prior art, as well as to file successive continuation or RCE applications. GSK would be willing to support any necessary statutory change. Any increase in fees should be reinvested into the PTO for hiring additional Examiners, enhancing training and providing additional incentives for Examiners, particularly senior level Supervisory Examiners, as well as for other PTO quality enhancement initiatives. A structure can be implemented that provides relief for small entities and patent applicants for whom this presents a hardship. We recommend that the small entity structure be reconsidered to reflect a true needs-based accommodation system.

2. The current practice at the USPTO of issuing one non-final Office Action followed by a final Office Action or Allowance is an impediment to high patent quality. This practice in most cases does not allow for a meaningful conversation between the Examiner and the Applicant ("conversation" implies more than one communication), and results in either claims being issued that would not be issued if reviewed more carefully (which creates unnecessary litigation), or claims not being issued that should be issued (perhaps with minor adjustments to the claims that could be negotiated) and which have to be re-filed in continuation or RCE applications, further increasing office backlog.

3. Providing Applicants with a reasonable number of options for the examination process would address differences in the complexity of different applications. Using this approach, Applicants could choose a fast track option which would provide expedited prosecution while providing Applicants with a commensurate scope of patent protection. Such an option would decrease overall application pendency.

4. A differentiated approach to examination based on the complexity of an application as measured by, for example, the number of references cited, scope and number of claims, complexity and technology of an application should be taken into consideration. The count system should be revised to provide additional counts and time allotments for examining complex applications, to conduct interviews and importantly, to issue more than one non-final Office Action. Conversely, Examiner conduct that may negate quality examinations, such as conducting a limited search based on a claim narrower than the broadest submitted claim, refusing an Applicant's written request for an interview or issuing multiple restriction requirements might be discouraged by some degree of count subtraction.

5. A three year non-extendable deferred examination alternative should be considered as a practical way to decrease the burden of backlogged applications at the PTO and improve overall

quality of the examination process. Experience from patent offices in other countries indicates that a meaningful percentage of patent applications are abandoned at the deferred examination deadline. This would help remove "stale" patent applications from the PTO docket system, and reduce unnecessary PTO workload.

6. The Patent Office should provide each Applicant with one comprehensive interview as of right, which can be either telephonic or in person. The Applicant should be able to choose at what point in the prosecution process to conduct the interview, as facts and situations vary among cases.

7. PTO/Industry working groups based on technologies should be established that are publicly transparent in order to provide further ideas and suggestions to the PTO to address examination issues at a grass roots level, to update the PTO on industry trends and issues identified during litigation, as well as the real world effect of PTO practices over time.

These recommendations are described in detail below.

Budget and Financial Incentives

Economics plays a major role in patent quality. As a stakeholder, GSK understands that the PTO must be adequately funded and staffed to succeed in its goal of issuing more high quality patents. For this reason, GSK is in favor of fee setting authority for the USPTO and strongly against diversion of PTO income to other areas of the federal government. The USPTO should not be used as a cost generating center for unrelated agencies, especially where the PTO is in such serious need of this income to achieve its objectives. GSK is aware that the USPTO does not fully control the issue of diversion, and therefore, stakeholders and the PTO should work actively together to achieve this goal. Fee setting authority in the absence of protection against diversion will likely not achieve the critical objective of enhancing patent quality.

GSK also recommends that the fee schedule be reconsidered to provide incentives for desired conduct. For example, at some point, successive continuation applications and RCEs should increase in cost. This would allow applicants to file such applications if needed but would add an additional consideration. Further, it is an inappropriate burden on the PTO to accept for review from the Applicant any number of references from 1 to possibly hundreds at no charge. GSK therefore suggests that the PTO consider charging for submission of art and references to be considered in a manner that reflects the actual burden on the office. For example, perhaps the first 20 references could be considered for a flat fee, and references after that considered on an increasing sliding scale of cost. In addition, perhaps an additional charge should be imposed for references of unduly long length. There should not be any requirement on the Applicant to characterize the art or references unless and until there is true inequitable conduct statutory reform.

GSK is aware that some users will be against fee increases (and GSK is against significant fee increases without protection against diversion or assurance that the funds will be used to primarily increase PTO service). However, for example, the PTO currently charges substantially less than the European Patent Office for the same work. Users who need relief from these fees should be granted an accommodation. The reduction should be based on financial

need, not size. There are some small entities that are very well financed and some large entities that are teetering on bankruptcy.

Non-final Office Actions

The current practice at the USPTO of issuing one non-final Office Action followed by a final Office Action or Allowance is an impediment to high patent quality. This practice in most cases does not allow for a meaningful conversation between the Examiner and the Applicant (a "conversation" implies more than one communication), and results in either claims being issued that would not be issued if reviewed more carefully (which creates unnecessary litigation), or claims not being issued that should be issued (perhaps with minor adjustments to the claims that could be negotiated) and which have to be refiled in continuation or RCE applications, which increases the office backlog.

We recognize that the PTO is supporting high quality comprehensive first searches and comprehensive first Office Actions on the merits, in which all of the issues are described to the Applicant. A tiered examination approach, as suggested above is aligned with the PTO in this objective. However, one of the objectives of the PTO, decreasing pendency of an application, can in many cases only be achieved by allowing at least one additional non-final Office Action after the first Office Action on the merits.

The Examiner, whose role it is to correctly applying the law, thereby protecting the rights of the applicant in patentable inventions and the rights of the public to have unpatentable claims rejected should work closely with the Applicant as a partner to understand the invention and to discuss and agree on the scope and language of the claims, even if this means several non-final Actions on the merits. Further, if the initial search fails to identify the most material references or other materials to the claimed subject matter, the Applicant is faced with a first Office Action on the merits that may not address all of the issues, particularly with broader claims and claims that overlap but represent patentably distinct subject matter. As a result, Applicant's response to the first Office Action on the merits may fall short in terms of addressing all the issues presented in the application. A second non final Office Action on the merits would help clarify claimed subject matter. This would also facilitate fewer restriction requirements and would further encourage addressing as many issues as early as possible in the examination process. Such a system could allow for resolution where only a few issues remain unresolved without the need to file RCEs or continuing applications, thus reducing overall pendency and burden on the PTO.

The PTO has requested that Applicant provide a comprehensive and clear response to Office Actions on the merits. We note that it may be necessary for Applicant to present an argument for lack of prima facie obviousness prior to a second round of communication submitting evidence that rebuts an obviousness rejection. While the PTO could encourage the Applicant to present evidence rebutting an obviousness rejection, it should allow the Applicant to also argue against prima facie obviousness, and if the Applicant does so, the Examiner should be required to substantively respond to and enter an amendment after a Final rejection.

The PTO should provide additional time allotments to enable Examiners to prepare and review second non-final Office Actions on the merits.

Fast track examination

In certain circumstances, Applicants need to have a patent issued rapidly to address market or other commercial needs. The PTO should consider providing Applicants with a fast track examination process. Implementation of a fast track option would be a non substantive change that would provide a means for better aligning Applicants needs with the overall burden of cases in the examination process. This would not supplant the current procedure for requesting accelerated examination (MPEP 708.82A). The fast track option could be accessed on payment of a reasonable fee.

A fast track option could be based on objective criteria for acceptance into the fast track, such as a limited number of claims with somewhat narrower than usual scope. In the case of novel chemical compounds, such as those often claimed in pharmaceutical applications, an example of a claim that would qualify for a fast track option might be directed to a narrow genus of compounds or specific compounds or their use or manufacture or so called "picture claims".

In addition, other criteria could be taken into consideration such as length of specification, number of working examples and number of references cited. For example, the PTO could advance examination of an application that cites no more than a specified range of references prior to the first Office Action on the merits. However, the PTO' request that Applicant specify the "best prior art" currently poses an unacceptable legal risk for Applicants without true inequitable conduct statutory reform. This is true because any characterization of the "best prior art" may become a basis for alleging inequitable conduct in later litigation. We can therefore, only support Applicants providing a list of material references or other art.

A fast track option would be an attractive solution for Applicants seeking patents with limited claim scope and would reduce overall pendency by diverting such fast track applications from the total backlog of cases.

Tiered examination process for applications

The PTO should consider differentiating (in addition to the fast track option discussed above) applications based on objective criteria that determine the degree of time and expertise required on the part of an Examiner during the examination process.

Such differences could be based on criteria such as, but not limited to, the underlying technology of the application, the overall length of the specification, number of working examples, number of references cited by the Applicant and number, type and scope of the claims. Based on these criteria, it would be possible to categorize each application. For example, a rating of 1 would be assigned to a very complex case based on the mentioned criteria, a rating of 2 would be of moderate complexity and a rating of 3 would be of low complexity. Each categorized application would then be tiered to the number of counts and the time allotment allowed for the initial search and subsequent examination process. A mechanism for Applicants to petition the category assigned by the Examiner and to interview with the Examiner solely to discuss category assignment would be suggested to ensure objectivity. Using this system, Examiners would receive sufficient time for a comprehensive initial search and review. The result would be an examination process aligned with the appropriate amount of time needed to complete a high quality comprehensive search and consideration based on the broadest claim and

complexity of the art. This would also help with providing Applicant with a comprehensive first Office Action on the merits.

In addition, under such a tiered approach, Examiners should be limited in the number of restriction requirements issued. Multiple restriction requirements are a significant concern in that they generate multiple applications that further burden the overall case load of the PTO. Applicants, faced with multiple restriction requirements face a more burdensome, time consuming and expensive prosecution process. By providing Examiners with tiered number counts and time allotment based on the complexity of an application, Examiners would be incentivized to complete a comprehensive first search, which in turn would provide a better quality first Office Action on the merits.

Application fees and possible other fees associated with a tiered examination process could be adjusted to allow for an increase in fees for more complex cases. While statutory considerations would need to be taken in to account, an increase in fee for more complex applications might be justified based on opportunity costs and would further provide incentives to Applicants to submit a comprehensive initial application with the appropriate scope and number of claims.

Deferred Examination

The PTO requested comments on a deferred examination period by Notice (FR/Vol. 74, No. 114). We support the implementation of an optional three year non-extendable deferred examination system subject to the below considerations, 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. When the patent application is filed, the Applicant could request immediate examination or defer examination for up to three years on payment of appropriate fees. However, The PTO should limit the deferral process period to three years to minimize the possibility that patent applications are merely filed for defensive purposes and allowed to remain pending for long periods.

The PTO should carefully consider both positive and negative implications of a deferred examination process. A deferred examination process needs to address key issues inherent in the pendency of the process, including prolonged public uncertainty as to the scope of issued claims as well as lack of clarity regarding freedom to operate. The PTO should, in any proposed deferred examination process, require that examination requests may be made by third parties, anonymously, if so requested, at any time during application pendency, followed by an expedited procedure for examination. This would lessen the potential for competitors to keep applications pending to monitor competitor's activities. In addition, The PTO should consider a rigorous analysis of the expected decrease in backlog to confirm potential benefits due to backlog reduction. These considerations should mitigate potentially adverse impact of a deferred process examination while providing for the benefits of such a process.

A deferred examination system has already successfully been in effect for many years in Japan, Canada, Germany, Korea and other important markets. Statistics in these countries affirm that a significant number of patent applications are abandoned by failure to request examination. This would have two positive outcomes for the USPTO: it would reduce PTO workload and eliminate stale cases from the PTO docket. 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

Interviews

We applaud the PTO for its support for interviews and its First Office Action Pilot Program. The PTO should continue to expand this pilot program. We support a program that gives each Applicant one comprehensive interview as of right, which the Applicant can use at a time during the prosecution that it considers the most helpful. If the Applicant requests the Interview, the Examiner should be given count credit for preparation and handling. Such interviews are invaluable for clarifying issues, understanding differences and resolving claim scope. To ensure productive use of interview time, the PTO should encourage Examiners to enter the interview with an allowable set of claims if possible. The Applicant could then work with the Examiner to resolve any issues with an agreed to allowable set of claims being the goal of the interview.

To enhance quality of interviews the PTO should encourage Examiners to prepare for meeting with the Applicant and to be ready to identify and discuss the basis for any and all outstanding rejections. Where possible, the presence of a Supervisory Examiner should be allowed to participate in an interview, upon request by the Applicant.

Face to face interviews are more likely to result in agreement and resolution of outstanding issues, and thus should be encouraged by the PTO. Language and communications issues that are sometimes encountered in telephonic interviews can be mitigated by such face to face interviews.

Formation of PTO/Industry Working Groups

The PTO should consider formation of PTO/Industry working groups by technology that would collaborate on enhancing quality by identifying issues that arise between Examiners and Applicants. These groups would, by clear and transparent discussion, discuss specific issues facing both the PTO and the users. The meetings can update the PTO on industry trends and issues identified during litigation, as well as the real world effect of PTO practices over time. The meetings can also address industry trends that Examiners may have concerns with in the examination process. Applicants may, on the other hand discuss issues they face, such as, multiple formalities rejections, patentability based rejections that arise late in prosecution and multiple restriction requirements. While the structure and implementation of these working groups would require significant input and organization, the results of such partnering and spirit of collaboration would have a positive impact on the overall quality of patents. Such working groups would not supplant the Patent Public Advisory Committee but would provide another forum that is specifically focused on practical, hands-on concerns involving the examination process.

Examiner Availability, Retention and Training

We understand that the PTO is able to hire more Examiners through the use of hotelling and remote working, and we support these accommodations. However, we also have a concern that it is more difficult to contact Examiners under these circumstances. We have also observed that junior Examiners may not get the same level of training where their supervisors are not physically located near them on a regular basis, which reduces the amount of informal training and mentoring. A mentoring program could facilitate enhanced interactions between more experienced and junior Examiners. Experienced Examiners are valuable and should be given extra merit based incentives.

Undersecretary Kappos has done an excellent job of giving the message to Examiners that their goal should be to grant valid patents, not reject applications. We applaud his efforts and encourage him to continue to voice this message.

Closing Remarks

GSK appreciates the opportunity to comment on the PTO's request for enhancement of quality in patents. We hope that our comments provided above are useful in developing creative and innovative solutions that will enhance patent quality. We look forward to partnering with the PTO to achieve these goals.

Respectfully yours,

Lorraine B. Ling

Vice President, Global Patents

GlaxoSmithKline