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DALLAS  
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NEW YORK  
SAN FRANCISCO

1501 K STREET, N.W.  
WASHINGTON, D.C. 20005  
TELEPHONE 202 736 8000  
FACSIMILE 202 736 8711  
www.sidley.com  
FOUNDED 1866

BEIJING  
GENEVA  
HONG KONG  
LONDON  
SHANGHAI  
SINGAPORE  
TOKYO

WRITER'S DIRECT NUMBER  
(202) 736-8914

WRITER'S E-MAIL ADDRESS  
jkushan@sidley.com

February 20, 2004

United States Patent and Trademark Office  
ATTN:Anggie Reilly  
Office of Congressional Relations  
Room 902  
2121 Crystal Drive  
Arlington, Virginia 22202

**RE: Response of Genentech to Request for Comments Regarding the Equities of Inter Partes Reexamination Proceedings (68 FR 75217 (Dec. 30, 2003))**

To Whom It May Concern,

I submit for your consideration, on behalf of Genentech, Inc., the following observations regarding the above-captioned request for comments.

Genentech strongly supports the creation of an effective, fair and expeditious post-grant review procedure that will permit re-evaluation of certain issues of patentability. Existing options for administrative review of patents (i.e., *ex parte* and *inter partes* reexamination procedures) are not balanced or effective, and are not viable or equitable options for reviewing patentability issues by parties other than the patent owner.

The notice solicits comments on six topics. Since Genentech has not been party to an *inter partes* reexamination proceeding (for reasons set forth below), we submit for your consideration remarks responsive to topics (1) and (3) through (6).

*Topic (1) Do you qualify as, or do you represent, a small entity?*

No. Genentech is a large entity.

*Topic (3) Are inter partes reexamination proceedings inequitable to any of the parties in interest?*

The *inter partes* reexamination system – by its legislative design – is inequitable to parties other than the patent owner who wish to have the Office conduct a thorough and effective review of validity of a patent. The inequities stem from the features that were incorporated into the legislation establishing the procedure with the intent of limiting its usability by third parties. Genentech’s concerns with the *inter partes* system stem from these legislative defects, rather than its implementation in the Patent and Trademark Office.

*Topic (4) What particular procedures or lack of procedures do you feel are inequitable?*

The most significant deficiencies of the *inter partes* reexamination system that adversely affect third parties can be summarized as follows.

1. The system cannot be used to review issues of validity concerning patents issued on applications filed before November 29, 1999. This renders the current system of marginal value to companies wishing to have an alternative to costly patent litigation in a Federal court.
2. The law imposes a “statutory estoppel” that prohibits a requestor from raising any issues of validity that “could have been raised” at the time of the request for reexamination in view of art known to the requestor. Moreover, this broad estoppel applies by the mere filing of a *request* for *inter partes* reexamination. Since many prior art-based validity issues require the use of experts and other evidentiary procedures available only in litigation in a Federal court, it is manifestly unfair to foreclose the ability of a third party to raise *any* issue of validity in a subsequent proceeding if a reexamination is requested on the basis of *one* issue. There is, simply put, no rational basis for imposing such a sweeping estoppel on third-party requestors, given the acknowledged limitations of the system relative to litigation in a Federal court.
3. The system also imposes a “fact” estoppel that prohibits a third party requestor from contesting the legitimacy of any “facts” determined in the proceeding. This uncodified provision imposes another penalty on third party requestors that can operate to limit the effectiveness or thoroughness of a review of validity of the patent undergoing reexamination. Again, there is no logical basis for creating this “artificial” estoppel provision given the constraints that exist in the system relative to litigation in a Federal district court.
4. The system does not permit the Office to review patentability issues that are most commonly encountered in biotechnology patents and applications; namely, compliance with §§101, and 112, first paragraph, excepting best mode considerations. This problem is compounded by the fact that many potential prior art issues depend, at least in part, on the construed scope of claims being evaluated.

On balance, the risks presented to a third party who seeks to review a patent through an *inter partes* reexamination proceeding far outweigh the potential benefit of having an “expert” adjudicator (i.e., the Patent and Trademark Office) assess the patentability question.

*Topic (5) What administrative action(s) should USPTO take to remove the identified inequities?*

Genentech believes that the problems with the present system should be solved by legislative action rather than administrative efforts.

*Topic (6) What legislative/statutory action(s) should Congress take to remove the identified inequities?*

Genentech believes it is possible to create by statute a post-grant review procedure that can provide a more cost-effective and expedited challenge to patent validity. In recent public discussions, a variety of models have been proposed, including by the Patent and Trademark Office in its 21<sup>st</sup> Century Strategic Plan. Two general concepts, in particular, have been articulated. One is to amend the existing authority to address some of the defects noted above. A second would be to establish a more structured and rigorous proceeding, modeled after post-grant opposition proceedings available in the European Patent Office (EPO) and other countries.

Genentech believes that the best path forward would be to create a “dual track” system that (i) preserves a viable *inter partes* reexamination model (i.e., one that addresses the deficiencies of the present system), but also (ii) provides parties with the opportunity to obtain more discovery in certain, well-defined situations. In this “dual track” model, the Office would make available additional discovery procedures (e.g., interrogatories, requests for admissions, cross-examination of expert witnesses, and oral hearings involving all parties) upon an appropriate showing by one or both parties. The additional showing could be part of an original request for review, or made within a finite period after commencement of an *inter partes* reexamination proceeding. If the additional showing is made, and found persuasive by the Office, the proceeding would be conducted by an administrative patent judge (or comparable administrative law judge), under proceedings comparable to those used in *inter partes* proceedings before the Board of Patent Appeals and Interferences.

Genentech believes it is important to preserve a “basic path” *inter partes* reexamination procedure because it would continue to make available a relatively low-cost proceeding to review clear-cut issues of patent validity. Such a procedure may not be suitable for proceedings that raise complicated issues of fact, but we assume that parties who commence such proceedings would be aware of the limitations of the system. Moreover, we believe there are many settings where a viable documentary procedure would be fully sufficient to address patentability questions that are based on contested fact issues. We are confident that, with a full and fair opportunity for participation, these factual and legal disputes can be adequately resolved by a well-trained PTO adjudicator.

#### Minimum Requirements of a Viable System

Regardless of its name or structure, Genentech believes that, at a minimum, a viable post-grant review procedure must have the following characteristics:

1. Scope: The system should permit review of questions of compliance with §101 and §112, first paragraph (other than best mode), in addition to §§102/103. It should not permit review of questions of inequitable conduct.
2. Estoppel. The system should not attempt to impose any special statutory estoppel on parties to the proceeding. At a minimum, the system should not create any estoppel effect as to issues that were not actually raised and fully litigated in the proceeding (i.e., by a final decision on the merits). In particular, the codified and uncodified estoppel provisions of the current law should be eliminated.
3. Preliminary Showing to Initiate Procedure – Parties wishing to commence a proceeding should be required to set forth (with appropriate evidence) a *prima facie* showing of invalidity of one or more claims. If such an initial showing is not made, the Office should not commence the proceeding.
4. Time Limits. The system should permit review of prior-art-based validity issues throughout the life of the patent. It should, however, require that third parties establish an additional justification for commencing a proceeding based solely on a §101 or §112, first paragraph issue, where that proceeding is commenced within a finite period of time from the issue date of the patent. The period of time should be longer than the 9 month period provided under the EPO regime. The additional showing could include (i) a disclosure of the real party in interest, (ii) a more substantial evidentiary showing (i.e., clear and convincing evidence of invalidity), (iii) a showing of threat of litigation comparable to that required to establish jurisdiction for commencing a declaratory judgment proceeding, (iv) the acceptance of more extensive estoppel conditions associated with the final outcome of the proceeding by the requestor, or (v) a showing of commercial interest in the patent, or some combination of these or other factors. In essence, the additional hurdle would ensure that after a certain period of time, the procedure would not be appropriate for raising certain issues of patentability unless truly merited.
5. Applicable to All Enforceable Patents. The system should enable the review of any patent that is capable of being enforced, subject to the threshold showings noted above.

These attributes can be grafted onto the existing *inter partes* reexamination authority through a relatively straightforward legislative amendment. Doing so would provide a viable procedure for reviewing a number of patentability questions that cannot be reviewed effectively or fairly under the existing system.

### Considerations Regarding a More Robust Proceeding

As noted above, Genentech believes it is possible and desirable to create a “dual-track” system that permits a more rigorous review of patent validity issues that would co-exist beside a modified *inter partes* reexamination system. The more rigorous procedure should permit greater discovery and should be managed by an administrative law judge with sufficient training and experience. Because these procedures will entail higher costs due to their more complex nature, they should be made available in a more limited circumstances than conventional *inter partes* reexamination procedures.

The specific details of the more robust proceeding merit careful consideration. In particular, the Office should avoid attempting to “recreate” the full-scale patent litigation environment available in Federal courts or the International Trade Commission (ITC). The compressed proceedings of the ITC, in particular, should not be considered to be a viable model for a post-grant system, as they are not less expensive or less complex proceedings compared to patent litigation in a district court. A post-grant system should complement, not attempt to recreate these more complex and expensive proceedings.

Thus, while Genentech supports making more rigorous procedures available in a post-grant administrative review proceeding, such procedures should be limited as to their nature and availability as follows.

1. Standing to obtain additional discovery. A party who believes it needs access to discovery (e.g., to address fact issues that it believes cannot be fairly addressed by filing declarations under 37 CFR §1.132, or where cross-examination of an opposing witness or party is considered essential to resolving a factual dispute) should be required to set forth the basis for such additional need. This could be done in an initial request, or by motion at an appropriate time after the Office has commenced an *inter partes* proceeding. If the showing was sufficient from the perspective of the PTO, the proceeding would be conducted by an administrative law judge (rather than a senior examiner in an *inter partes* reexamination proceeding), and certain additional discovery options would be made available to all parties to the proceeding.
2. Nature of additional discovery permitted. Genentech believes that only certain types of discovery would be appropriate in a more rigorous post-grant proceeding. Specifically, such proceedings should permit (subject to the discretion of the administrative patent judge) (i) limited requests for admissions, (ii) a limited number of interrogatories, (iii) cross-examination (by deposition or in a hearing) of expert witnesses relied upon by the opposing party, and (iv) the opportunity for an oral hearing. Other types of discovery should be prohibited. In particular, parties should not be subject to document production, or forced to produce individuals for depositions (other than expert witnesses put forth by the party in support of its case). Such limitations are appropriate and will not undermine the effectiveness of the procedure, particularly in view of the fact that the PTO is an “expert adjudicator” that is able to independently evaluate fact conflicts. Such

limitations also will ensure that the procedure do not replicate the functions – along with the cost and complexity – of full-scale litigation in a Federal court.

3. Higher Fee. A party that wishes to have access to the enhanced discovery under a more rigorous procedure should be required to pay a fee that corresponds to the additional costs such a proceeding would pose for the PTO.
4. Authority to delegate fact disputes. The PTO faces annual challenges and uncertainty in its funding. In view of this, it would be desirable for Congress to allow the PTO to delegate responsibility to private parties to resolve certain fact issues. For example, as is the case with the existing interference authority, the PTO may allow parties to arbitrate certain issues. In a similar fashion, the PTO could allow a third-party mediator or arbitrator to adjudicate certain conflicts, and then to rely on those findings in making its patentability determinations. This authority may be useful to have to ensure that funding problems do not adversely affect the progress of cases that have been commenced.

In summary, Genentech strongly supports efforts to improve the existing post-grant opposition system. The current system is inequitable due to inherent flaws in its design, and largely unusable as an effective means of reviewing issues of patent validity.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Kushan", with a long horizontal flourish extending to the right.

Jeffrey P. Kushan  
(Submitted on behalf of Genentech, Inc.)