

May 26, 2000

VIA FACSIMILE: (703) 872-9411 (4 PAGES TOTAL)

The Honorable Q. Todd Dickinson  
Under Secretary of Intellectual Property and  
Director of the United States Patent and Trademark Office  
Box Comments – Patents  
Assistant Commissioner for Patents  
Washington, DC 20231

ATTENTION: Robert Bahr  
Comments on Proposed Changes to Implement 18-Month  
Publication of Patent Applications (65 FR 17946)

Dear Director Dickinson:

On behalf of Genentech, Inc., I am pleased to offer comments on the proposed system and rules to implement the 18-month publication of patent applications. Genentech is a biotechnology company based in South San Francisco, California. The corporate mission of Genentech is to use human genetic information to develop, manufacture and market pharmaceuticals that address significant unmet medical needs

Let me begin by commending you and your staff for the quality of the proposed rule package. We appreciate that it must have been a nearly Herculean effort to complete the rule package within the short window of time provided under the statute. The overall accuracy and faithfulness of the proposed rules to the statute is to be commended.

However, we believe there are a four areas where further refinement or clarification of the rules is warranted. Several of the concerns we have are ones that also have been mentioned by the Biotechnology Industry Organization (BIO) in its comments on the rule package. We encourage the Patent and Trademark Office (PTO) to make discrete changes to the rules in light of our following comments, in the interest of making sure that the publication of patent applications and patent term adjustments is administered in a manner that is efficient and fair for patent applicants as well as the public.

First, it has been our experience that the integrity of official file wrappers, and the ability of the PTO to maintain control over the contents of the file wrappers, is often compromised when third parties request copies of those materials. Corruption of the integrity of the file wrapper and the loss of papers (and often the entire file wrapper) is all too frequent an occurrence. Moreover, we are concerned that by allowing third parties to obtain copies of wrappers for patent applications while they are still pending and under examination will be very disruptive of the examination process. For those several reasons, we strongly urge that the PTO not permit third parties to request and obtain copies of file wrappers for pending applications until such time that the PTO can prepare copies of such file wrappers from electronic, rather than paper records.

Second, the PTO should provide much clearer guidance on the issue of sequence listing deposits, and should implement significant further improvements to its sequence listing authoring and transmission systems if it intends to impose strict time deadlines on patent applicants with respect to sequence listings. Our experiences in preparing sequence listings reveals that notwithstanding a significant amount of effort on our part or on the part of our outside counsel, these submissions are often found by the PTO to fall short of the PTO's requirements. In many instances, it can take three to six months to put these sequence listings into "proper" order.

The rule package mentions the issue of sequence listings almost in passing. From the discussion on drawings, it seems likely that the PTO will not hold in abeyance deficiencies with regard to sequence listings. More significantly, we note that a failure to comply with the sequence listing formality requirements will be deemed to be a failure to diligently conclude prosecution of the application, which could become the basis of a reduction of a potential patent term adjustment under 37 CFR 1.704(c)(9). Clearly, this issue is more than just a simple concern over formalities.

We believe the rule package should specify precisely which of the requirements under sections 37 CFR 1.821 to 1.825 must be satisfied in order to meet the PTO's requirements for publication of applications containing sequence listings. Preferably, the Office will confirm that the provision of a drawing containing sequences where such drawings comply with the applicable rules governing drawings will not delay the publication process. Moreover, we believe the PTO should set a specific period during which compliance can be met with the sequence listing deposit rules, so that a reasonable period is available for applicants to respond to deficiencies that are identified by the PTO without affecting potential patent term adjustment.

Third, we believe a number of significant changes must be made to the proposed procedure that will permit third parties to submit patents or publications during the PTO's examination of a patent application. As presently contemplated, a third party may submit

such documents within two months from the date of publication or prior to the notice of allowance, whichever is earlier.

The proposed procedure for such third party submissions poses serious risks for abuse. We recognize the benefits that this type of opportunity may present in improving the quality of patent examination in technological areas that do not have the benefit of vast collections of searchable prior art (i.e., not the biotechnology industry). Yet, as proposed, the system leaves too many opportunities for third parties to inundate the PTO with irrelevant submissions, anonymously harass patent applicants, and cause unwarranted and prejudicial delay in the examination process for the time that it takes an examiner to consider whether submitted references are pertinent to patentability. In this regard, we note the strong message against allowing for pre-grant opposition that was contained in the American Inventors Protection Act of 1999, as part of the publication system.

Assuming that some form of this procedure will be included in the final rule package, we urge the PTO to make a number of amendments to it that will foreclose to the maximum degree possible the abuse of this procedure. In particular, we recommend the following:

- Require disclosure of identity of third parties. Third parties that submit information to the PTO should be required to identify themselves on the record, and in a manner that will ensure the accuracy and veracity of their disclosure (e.g., under the requirement of a declaration or oath). Third parties also should be required to identify whether they are acting within the scope of an agency relationship, and if so, to disclose the identity of the principal directing their actions.
- Require that the third party serve disclosures on patent applicant. Rule 1.99(c) requires that the documents cited to the PTO be served on the patent applicant. The rule does not specify who is obliged to serve the documents. We believe it is appropriate for the third party to take on this responsibility of serving the patent applicant with the documents being cited. This will help ensure that frivolous disclosures are avoided, and that proper notice is provided to the patent applicant.
- Limit number of references to five per submission. The present proposed rule would allow a third party to cite up to twenty references in a single submission. We are concerned that by setting the threshold this high, third parties will find it easy to file numerous irrelevant and/or cumulative patents and publications simply because there is an opportunity to do so. Limiting the citations to five per submission will force a more careful evaluation of prior

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art by third parties, and will reduce the burden on the PTO and the applicant to respond to references cited under this authority.

One other issue that should be clarified is in regard to the time limit within which third parties may submit such references. The PTO is proposing to permit third parties to avoid the time limit specified in the rules where the “patents or printed publications could not have been submitted to the Office earlier.” We are uncertain whether this standard, when applied, will be stricter or more lenient than the “unavoidable” standard now employed by the PTO in numerous other circumstances.

Fourth, the PTO should provide a transitional publication arrangement for patent applications that, by operation of a claim under 35 USC 120, will be required to be published on or after the date that they are filed once the law comes into effect. In this regard, we note that the proposed rules require patent applicants to be in full compliance with all requirements for publication on the date that the application is filed. It would seem reasonable to provide for a specified period of time following the filing date that would not give rise to a finding of “delay” that would then serve as the basis for potentially reducing the adjusted term of the patent. At a minimum, the PTO should be prepared to act on these applications expeditiously to communicate any deficiencies as soon as possible to the applicant.

Thank you for considering our comments.

Very truly yours,  
GENENTECH, INC.

Sean A. Johnston  
Vice President, Intellectual Property