

# Genentech, Inc.

## LEGAL DEPARTMENT

1 DNA Way  
South San Francisco, CA 94080-4990  
(650) 225-1000  
FAX: (650) 952-9881 or (650) 952-9882

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**By facsimile – (703) 872-9411**

The Honorable Commissioner for Patents  
Box Comments – Patents  
Washington, DC 20231

ATTENTION: Eugenia A. Jones

Dear Sir:

This letter responds to the notice entitled "Elimination of Continued Prosecution Application Practice as to Utility and Plant Patent Applications," published at 66 F.R. 35673 (July 9, 2001). The following comments are submitted on behalf of Genentech, Inc. Genentech is a biotechnology company based in South San Francisco, California, whose corporate mission is to use human genetic information to develop, manufacture and market pharmaceuticals that address significant unmet medical needs.

Genentech is currently prosecuting a large number of utility applications before the U.S. Patent and Trademark Office (PTO). A significant number of our active applications were filed during a period that makes them subject to the regulations promulgated by the PTO to provide for the possibility of continued prosecution practice.

Genentech does not favor the elimination of Continued Prosecution Application ("CPA") practice. Neither of the available alternatives, namely, a Request for Continued Examination ("RCE") under 37 C.F.R. § 1.114 or a continuing application filed under § 1.53(b), provides the flexibility of CPA practice with the equivalent legal effect. The elimination of CPA practice would thus impose significant burdens and a substantial impediment to efficient prosecution in those applications for which it is now available.

CPA filings are available only for certain applications; namely, those filed before May 29, 2000. 37 C.F.R. § 1.53(d)(1)(i)(A). CPA applications, like the corresponding RCE procedure applicable to applications filed after May 29, 2000, provide a number of

administrative efficiencies. Both mechanisms use the same file wrapper, continue prosecution before the same examiner, and avoid the need to "re-create" the prosecution history of the parent application (i.e., to impose rejections and provide responses to rejections relating to issues previously resolved). We note particularly the advantages of the latter feature. In our experience, the submission of copies of amendments from parent applications has more often than not led to confusion and garbled file wrappers. Also, like RCEs, CPAs expedite continued examination because they are processed by the applications examiner that supports the patent examiner, and once entered, they are placed on the examiner's amended applications docket.

Unlike a RCE, however, a CPA enjoys the legal status of a new utility application filed under 35 U.S.C. § 111(a). A CPA filed on or after November 29, 2000, will therefore be published pursuant to § 122(b) and will be eligible for patent term adjustment under § 154(b) and provisional rights under § 154(d). It will also be subject to the revised terms of 35 U.S.C. § 103(c). While an applicant who chooses to file an RCE will gain most of the efficiencies of CPA practice, she will not have the benefit of the rights made available through the American Inventors Protection Act ("AIPA"). Additionally, a RCE cannot be used to pursue subject matter not elected pursuant to a restriction requirement under 35 U.S.C. § 121 in the underlying application, as can a divisional application filed as a CPA.

In its Federal Register notice, the Office cites the cost and inefficiency of publishing CPA filings as the primary reason favoring the elimination of CPA practice. We believe, however, that if the only available choices are a new § 1.54(b) filing and a RCE, many applicants will choose to gain the benefits of patent term adjustment and provisional rights provided by 35 U.S.C. § 154. We also believe that significant administrative burdens will be placed on the Office as a result of the filing of new continuing or divisional applications under 37 C.F.R. § 1.54(b) in place of CPAs.

In particular, unlike a CPA, a new § 54(b) application –

will require greater time and Office resources to process than does a RCE;

will be taken up for examination in turn with all other new applications, thus lengthening the average time between filing and first action, as well as deferring the conclusion of prosecution by (typically) at least 12 months;

will require the filing of new Information Disclosure Statements in the continuing application, with the consequent need for the examiner to retrieve copies of references from the prior applications in which they were first cited (assuming that the references have in fact remained with the file, which is in our experience an uncertain prospect);

will require the filing, processing, and recording of new terminal disclaimers, usually submitted only after the examiner has newly reviewed all of the relevant files and set forth appropriate double patenting rejections on the written record; and

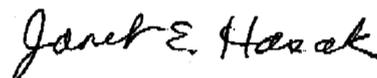
generally will increase the number of documents which the Office must process and the number of files it must store.

Unfortunately, many of the new administrative burdens will create new responsibilities for the patent applicant. For example, because the required format for filing amendments has recently changed, 37 C.F.R. § 1.121 (2000), even the relatively simple act of amending a continuing application to match the prosecution history of a prior application will involve a significant additional amount of clerical labor and professional review. Moreover, due to attrition within the examining corps and imperfections in the Office's docketing procedures, any newly filed application is at risk of being reviewed by an examiner other than the one who prosecuted the prior application. Such serial examination results in inefficient prosecution and, because of differences in practice between examiners, most often works to the detriment of the applicant.

In summary, Genentech does not agree that "there no longer appears to be a need for [CPA] practice," as the Office's Federal Register notice asserts. A CPA provides a number of procedural advantages that expedite the conclusion of prosecution coupled with the legal advantages of a new application filed under 35 U.S.C. § 111(a). A RCE is not the legal equivalent of a CPA, and from the perspective of the patent applicant, it can often be an inferior mechanism for continuing prosecution of an application. It has been Genentech's practice to file CPAs in preference to RCEs whenever appropriate, and Genentech has made a number of business decisions based on the belief that CPA practice would continue to be available to existing qualifying applications.

Finally, we do not believe action is needed to terminate CPA practice in view of the fact that the number of applications that will be eligible to use this mechanism will, by the natural process of examination, diminish to a negligible point in the next few years. As noted above, CPAs are only available for applications filed prior to May 29, 2000. We acknowledge that it is more cumbersome for the Office to publish a CPA than a new § 1.54(b) continuation application. However, the costs borne by the Office in publishing such applications are more than offset by the relative efficiencies of CPA practice – efficiencies that benefit both the Office and the patent applicant. We therefore urge the PTO to retain 37 C.F.R. 1.54(d) in its current form.

Respectfully submitted,



Janet E. Hasak  
Associate General Counsel - Patent Law  
Genentech, Inc.