

November 12, 2003

**By electronic mail – AB64.comments@uspto.gov**

Mail Stop Comments – Patents  
Commissioner for Patents  
Attention: Hiram Bernstein  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Re: *Changes To Support Implementation of the ... 21st Century Strategic Plan;  
Proposed Rule*, 68 Fed. Reg. 53816 (Sep. 12, 2003)

Dear Mr. Bernstein:

Genentech, Inc. (“Genentech”) offers the following comments in response to the Office’s Notice of proposed rulemaking.

Genentech is a biotechnology company based in South San Francisco, California. Our mission is to be the leading biotechnology company, using human genetic information to discover, develop, manufacture and commercialize biotherapeutics that address significant unmet medical needs. Genentech commits itself to high standards of integrity in contributing to the best interests of patients, the medical profession, our employees and our communities, and to seeking significant return to our stockholders based on the continued pursuit of excellent science.

We rely on obtaining timely and effective patent protection to support our business activities. Since Genentech was founded more than 25 years ago, we have filed thousands of patent applications to protect our inventions, and we continue to file new applications on a regular basis. At any given time, we have hundreds of applications pending before the Office.

We support the Office’s efforts to make its operations more efficient and improve the patent examination process. We believe that many of the proposed rule changes will serve those goals. With respect to several of the proposals, however, we are concerned that the rules as presented would have unintended or undesirable consequences. Accordingly, we offer the following comments on specific proposed rules.

**A. § 1.55 – Continuity of § 119 Priority Claims in Parent Applications**

The proposed requirement for a continuous chain of § 119 priority claims in prior applications would parallel practice involving § 120 claims, and we see no substantial difficulties with the requirement going forward. However, if the rule is construed to apply retroactively, it could be exceptionally burdensome in some cases. The proposed rule and the accompanying discussion do not state how the rule would be applied with respect to parent applications that may already be patented or abandoned.

We urge the PTO to apply the requirement for express § 119 claims only to priority applications filed on or after the effective date of the rule, and to clearly state as much in connection with the promulgation of a final rule. Such a limitation would not detract from the objective of providing conspicuous notice that a newly filed application may be subject to publication less than 18 months from its filing date.

#### **B. § 1.57 – Incorporation by Reference**

We generally support the initiative to clarify the incorporation by reference practice. We also see considerable value in the Office’s “safety net” proposal to incorporate § 120 priority applications for the purpose of recovering “obviously omitted” pages or drawings in a continuing application filing.

We believe that in connection with the promulgation of the rule, the Office should restate what constitutes a proper incorporation by reference. We are aware of instances in which applicants have relied on “blanket” incorporation statements as the basis for selectively inserting disclosure from priority applications into late-generation continuations. In effect, such insertions create new disclosure by concatenation. Such practices do not seem consistent with the intent of the legal precedent governing incorporation practice. *See In re de Seversky*, 474 F.2d 671, 674 (C.C.P.A. 1973) (incorporating document must “clearly identify[ ] the subject matter which is incorporated and where it is to be found”), cited at M.P.E.P. § 608.01(p); *see also Advanced Display Sys., Inc. v Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (“To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.”).

We do not believe that it would be practical or desirable for the PTO to attempt to define every scenario of a proper incorporation by reference practice. However, we encourage the Office to state explicitly that simply identifying an incorporated patent or publication does not necessarily “immunize” any future amendment of the disclosure against new matter, particularly when subject matter is selectively incorporated from the cited document on the basis of a generic or “blanket” incorporation statement.

#### **C. § 1.83(a) – Prohibition of Duplicated Figures and Sequence Listings**

The Office’s proposal to prohibit the duplication of the same sequence information in two sections of the specification is rational. However, the proposed amendment to § 1.83(a) does not take into account the fact that some kinds of information related to sequences cannot be presented in sequence listings. For example, domain structures, stack plots showing sequence alignments and conserved residues, *etc.*, can only be shown through figures. We urge the PTO to clarify that placing sequence data both in a sequence listing and in figures is fully proper when the figures convey information that is not present in the listing.

#### **D. § 1.105 – Requests by Examiners for Information**

We believe that in many instances, requests for information are appropriate tools to make more efficient use of examination resources. Where the applicant has ready access to well-known facts, or is otherwise willing to remove such facts from contention, interrogatories and stipulations will serve the goal of compact prosecution. They can also contribute to more transparent prosecution and more complete file wrappers, objectives we generally support.

Notwithstanding this, we believe the discussion of the proposed rule outlines an overbroad conception of the proper role of requests for “information” in patent prosecution. We are especially concerned that several of the requests that are offered for illustration call for conclusions of legal analysis rather than objective facts (*e.g.*, “[a]pplicant’s interpretation of the distinctions among claims,” or “applicant’s interpretation for the intended breadth of claim terms,” *id.*). While it is reasonable for an examiner to invite comment on such questions as a consequence of evaluating support for the claim or relevance to prior art, it would not be appropriate to treat an attorney’s or inventor’s response to a legal inquiry as a fact. We note that such “facts” could become effectively uncontestable, not only in the course of the prosecution, but also in subsequent appeals or litigation involving the patent.

We are also wary of the proposed reference in draft § 1.105(a)(4) to the “opinion[s]” of the persons from whom information is requested. Such opinions would not necessarily be relevant evidence for any determination that the Office is required to make. For example, while an inventor’s opinion concerning the level of skill in the art would be relevant for making a determination regarding the level of skill, an attorney’s opinion on that question would not. Requests for “opinion” information must be particularly focused on the person(s) whose opinions would in fact be relevant to the question raised by the Office. We also believe that a statement of counsel to the effect that the opinion of certain persons would not be relevant as to the particular question(s) at issue should be accepted by the Office as a complete response to an improperly directed requirement.

Finally, we urge the PTO to establish procedures that will ensure that the authority of Rule 105 is exercised properly and in appropriate circumstances. In addition, we believe it is important for the Office to invest sufficient resources to train examiners to draw appropriate distinctions between facts, in the sense of objective evidence, and *questions* of fact. An example of the latter is whether the disclosure complies with the written description requirement in respect of a claim. Making determinations on such questions is the examiner’s job in the first instance.

Accordingly, we believe it would be useful and appropriate for the Office to develop relatively detailed guidelines and training examples for the use of the authority to request information. We also urge the PTO to employ a heightened level of supervisory review for “expanded” Rule 105 requests, so that inexperienced examiners will not be allowed to use the authority in inappropriate circumstances.

### **E. § 1.111(a)(2) – Supplemental Replies to Non-Final Actions**

The discussion of proposed § 1.111(a)(2) examines at considerable length why supplemental amendments are burdensome. In our view, however, the solution the Office proposes – the almost categorical prohibition of supplemental replies – is simplistic and unreasonable. In many circumstances, a supplemental amendment is the most straightforward, expedient, and efficient means of advancing prosecution. Among these we count corrections of typographical errors, submissions of executed declarations identical in content to unexecuted declarations submitted for the examiner’s review in a first reply, and submissions of ministerial supporting documents that the applicant desires to make of record (*e.g.*, documents supporting a biological deposit with ATCC).

We believe that in all such situations, the rule should affirmatively provide the examiner discretionary authority to enter a supplemental amendment. We urge the Office to redraft the rule to provide discretionary authority for the entry of all supplemental amendments filed before the mailing of a subsequent Office action. The Office should also provide substantial guidance in the M.P.E.P. indicating exemplary circumstances in which the Office believes that examiners should exercise their discretion to enter papers.<sup>1</sup>

The alternative procedures the Office proposes for securing later review of non-entered amendments are unreasonably cumbersome and would place disproportionate burdens on applicants. For example, it suggests that applicants should file continuing applications to ensure consideration of supplemental replies. We believe that in the great majority of cases, it would tax the Office’s resources significantly to receive a new application and duplicate the examination effort that had already been invested in the case.

We note that the discussion of the proposed rule states correctly that current rules do not provide for RCE filings in applications that have not been finally rejected. We believe that a regulatory solution, either expanding RCE practice or devising some other appropriate procedure and fee for continued examination in these circumstances, would be appropriate.<sup>2</sup> We urge the PTO to consider such a regulatory solution before implementing the present proposal to amend § 1.111.

Finally, draft § 1.111(a)(2) is ambiguous and likely to lead to confusion. We believe that these drafting ambiguities should be rectified before any amended rule goes into effect. In particular, the discussion of the proposed rule states that supplemental amendments filed after the period for response had run would not be reviewed or considered. However, the rule itself is silent as to such amendments. The rule also provides discretionary authority for the examiner to

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<sup>1</sup> The problem of papers “crossing in the mail” could be addressed by providing by rule that the Office will not in any circumstances enter a supplemental reply that is placed in the file after an Office action has been mailed.

<sup>2</sup> 37 C.F.R. § 1.114, which governs RCE practice, requires that prosecution in the application be closed before a submission under that section may be entered. The statutory authority for continued examination, 35 U.S.C. § 132(b), does not contain this restriction. Thus, the Office may provide by rule for the continued examination of applications that have not been finally rejected.

enter and consider a limited class of amendments, but it fails to state whether the examiner has similar authority or no authority to consider other amendments.

We also foresee considerable disagreement between applicants and the Office about whether a supplemental amendment would be entitled to entry as “[p]lac[ing] the application in condition for allowance” (§ 1.111(a)(2)(i)(C)). In any event, as a practical matter, that question can only be evaluated *after* an amendment has been entered and considered. It would be illogical to provide that certain amendments will be denied entry because their consideration would be burdensome after they have been reviewed and considered.

#### **F. § 1.115 – Preliminary Amendments as Part of the Original Disclosure**

We believe the proposed changes to § 1.115 would raise significant problems, and we urge the PTO to not adopt them.

As the PTO outlines its proposal, the examiner would review the preliminary amendment for added matter and require a new declaration if any new matter is added by the amendment. Under current practice, however, the examiner is also directed not to consider “filing date” issues in CIPs unless there is intervening prior art. In view of this longstanding practice, we are skeptical that all preliminary amendments, once filed, would be fully reviewed and properly treated by examiners.

We also believe that the automatic inclusion of preliminary amendments as part of the “original disclosure” could have substantial adverse effects where an applicant intends not to add new disclosure, but the examiner nonetheless holds the amendment presents “new matter.” The disagreement could lead to substantial administrative delays in prosecution. In short, the detriments of adopting the proposed change far outweigh any benefits to efficient examination and operation of the Office.

#### **Conclusion**

We commend the Office for taking the initiative to modernize its practice. We appreciate the opportunity to present these comments and hope they will be helpful.

Yours sincerely,

Mark T. Kresnak, Ph.D.

Section Patent Counsel

Genentech, Inc.