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LEGAL DEPARTMENT

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January 26, 2004

By electronic mail – BPAI.Rules@uspto.gov

Mail Stop Interference
Jon Dudas
Acting Director, U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Re: *Rules of Practice Before the Board of Patent Appeals and Interferences*, 68 Fed. Reg. 66648 (November 26, 2003)

Dear Director Dudas:

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.

Patents are a fundamental aspect of our business. 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 typically have hundreds of applications pending before the Office. Due to the nature of our industry and the evolution of the law, many of our cases are involved in appeals and interferences.

Specific Comments

We offer the following comments with respect to the noted sections of proposed Part 41 of title 37 of the C.F.R.

§ 41.7

We believe that an unqualified authority to expunge papers from pending appeals and interferences is inappropriate. We strongly support the goal of removing duplicative papers from the Office's records, but we believe that the rule should be more precisely delineated. In this case, express language in § 41.7(a) limiting its application to "exceptional circumstances" would be reasonable, and further amplification (and perhaps, illustration) of the Office's intent in the discussion of the rule is in order.

§ 41.33

We appreciate the importance of concluding prosecution in patent applications before they are referred to the Board on appeal. Apart from the Board's legitimate concerns with efficiency, it is invariably our experience that the best decisions and the best records result from the appeals that present the relevant issues cleanly. Nevertheless, we believe that the proposed rule would unnecessarily curtail desirable aspects of current prosecution practice and, in some cases, would actually complicate the appeal process.

Like most applicants, we use Notices of Appeal as a component of our after-final practice. We often resolve issues productively by continuing negotiations with the examiner after we file a Notice. Many of those cases result in allowances rather than appeals. We would favor no change to the standards now employed for admitting amendments after a Notice of Appeal. If there are particular problems or abuses that have prompted the proposed change to the rules, we encourage the Board to discuss them with practitioners, either through a Request for Comments or in the context of meetings of patent bar organizations.

Even if the Office has determined that more stringent standards are needed, we believe that there is room for a reasonable middle ground. We suggest that the examiner be allowed to enter amendments to *existing* claims that, in his or her discretion, *resolve* issues that would otherwise be appealed. Such a rule would clearly limit the permissible amendments to those that completely removed appealable issues from the case. This would be a somewhat higher standard than current Rule 116. At worst, this standard would simplify many appeals. Often it would avoid the need for appeals to the Board altogether.

We also observe that the rule governing practice before the examiner prior to the filing of an appeal brief should remain in Part 1 of 37 C.F.R.

§ 41.37(c)(1)(ii)

We support the inclusion of a requirement that appellants identify prior and copending proceedings that may affect an appeal. We are concerned that the rule as drafted is ambiguous with respect to the scope of “other prior or pending appeals, interferences or judicial proceedings ... which may be related to, directly affect or be directly affected by or have a bearing on the Board’s decision.” Read broadly, this would require an appellant to identify *every* precedential decision that might bear on the issues on appeal.

The ambiguity will frustrate the Board’s objective in promulgating the rule and could expose appellants to unreasonable allegations of inequitable conduct. Further discussion or clarification by the Office would be helpful. We suggest that several examples of relationships that would require notice under the rule (e.g., common subject matter, claim to a common priority application) or would not do so (e.g., prior cases involving other parties) would help convey the Office’s intent.

§§ 41.37(c)(1)(iv) and § 41.110(b)

To the extent that the Office is trying to promote the concise presentation of facts relevant to evaluating an appeal, we support the proposed requirement for page-and-line citations of support for claim limitations. We are concerned that an appellant’s statements pursuant to this rule could, however, be cited improperly by an adverse party in later litigation to support a limiting claim construction or an estoppel argument.

An appellant could reasonably limit its statement under § 41.37(c)(1)(iv) to particular embodiments or aspects of the invention that are relevant to the issues on appeal. Every appellant owes a duty of candor to the Board to fully explain the relevant aspects of its invention and the manner in which the aspects relevant to the appeal are supported by the patent specification. More practically, it is always in the appellant’s interest to do so. These considerations suggest that any statement filed to comply with the rule would be sufficiently complete to allow the Board to review the appeal efficiently and properly.

For these reasons, we believe that, as appropriate to the facts of the case, an appellant’s statement under § 41.37(c)(1)(iv) would not necessarily represent the full scope of the invention. In our view, an estoppel effect in such circumstances would be unwarranted. We therefore request that the Office clarify that the rule is promulgated only as a procedural device.

For similar reasons, we believe that the proposed requirement of § 41.110(b), calling for indications of support in the specification of claims in interference, should likewise be regarded as a procedural tool rather than a substantive requirement.

§ 41.39

We support the proposal to permit new grounds of rejection in examiners' answers, but with an additional option for response to gain the greatest benefit from the revised practice.

In some circumstances, it is most efficient to address "side issues" without diverting the appeal process. The examiner may discover, for example, that some of the claims are formally deficient (e.g., a term lacking an antecedent or depending from a canceled claim) or have some other inadvertent defect. Rejections of this nature should be treated on the written record, but the delay involved in reopening prosecution is not appropriate.

An option for appellants to file at least amendments that address the new rejections would be desirable. If, in the examiner's view, the amendments resolved the issue, he or she could simply withdraw the new rejections. In that case, the appeal would be placed in a better form for consideration by the Board. If the issues were not resolved, the examiner could reopen prosecution.

We also believe that the public, examiners, and the Board would gain benefit from further illustration of the circumstances in which the Office envisions that new grounds of rejections in examiners' answers would be appropriate. The three examples that accompany the discussion of the proposed rule are helpful, but they are limited in scope. We suggest that additional examples of both "acceptable" and "unacceptable" new grounds of rejection should accompany any final rule to clarify the intended practice.

§ 41.102

The proposed rule would require that the examination of applications be "completed" and at least one claim be allowable before an interference or other contested proceeding be initiated. We believe that the rule creates some confusion in view of the Office's evident intent to continue the practice of allowing a junior applicant to provoke an interference by demonstrating *prima facie* that it is entitled to judgment relative to a senior patentee. On such fact, the pending application should stand rejected under 35 U.S.C. § 102(e). But under current Rule 608, an interference can (and should) go forward.

We suggest that the Office incorporate into § 41.102 the language of current § 1.607(b), which requires the presence of "interfering subject matter ... which is patentable to the applicant subject to a judgment in an interference." Including this language would accommodate the current practice under Rule 608.

§ 41.106(b)(4)

The Office proposes requiring parallel case citations to a West reporter and the USPQ in interference papers, citing the Federal Circuit's practice in this regard. But the CAFC has recently revised its rule to delete the requirement for parallel citations. In our view, the convenience of the Office outweighs the inconvenience to applicants of tracking down

duplicative citations. We also note that costs of database access for such exercises would be a substantial burden for some applicants.

We suggest deleting the proposed rule.

§ 41.108

We agree that going forward, the proposal to discontinue the practice of expunging declarations under Rule 131 and statements under Rule 608 from application files in interference is reasonable and appropriate. We are concerned, though, that the change in practice runs counter to the expectations of many who filed their applications prior to the enactment of the pre-grant publication authority. Such applicants have prosecuted their applications with the expectation that the applications would be maintained in confidence until grant, and in particular that Rule 131 declarations and Rule 608 statements would not be at issue in interferences.

We expect that there are relatively few remaining applications for which the proposed change in practice would in fact make a difference. Nonetheless, those applications have been filed and prosecuted in light of longstanding practices and well-settled expectations at odds with the proposed rule. We therefore suggest that applications filed prior to November 29, 2000, be “grandfathered” under this rule so as to be entitled to the expungement practice under current Rule 612.

§ 41.121

We generally support limiting motions in interference to issues that are germane to the interference. We think it unwise, however, to limit the Board’s authority by rule to consider other motions on questions within its statutory authority. In particular, we believe that the Board should have clear flexibility under the rules to consider, as it sees fit, motions regarding the patentability of the opponent’s claims. We suggest that a provision allowing the Board to consider and grant such motions “when justice requires” would appropriately limit the frequency of such motions.

§ 41.201

We support the proposed definition of a “constructive reduction to practice.” However, we believe that the terminology could lead to confusion as the law develops. It is critical that it be understood that the regulatory definition applies only in the context of interference procedure and is limited to the evaluation of embodiments. The concept of a constructive reduction to practice in patent law generally is broader; in particular, it often applies to claims rather than embodiments. We believe it would be improper and inappropriate to impose the administrative definition in any context outside interference.

Under the law of interferences, it is longstanding practice that a party may prevail as to a generic count by establishing the constructive reduction to practice of a species within the genus. We note that the unqualified application of this practice might conflict in some circumstances

with case law holding that the written description and enablement of a single species may not be “representative” of a claimed genus, and will thus not establish “possession” of the generic invention in every case.

We believe that future cases may explore this conflict. To avoid confusion in applying the priority-based concept of the constructive reduction to practice of embodiments, and to distinguish the concept of the constructive reduction to practice of an invention, we suggest that more precise terminology will be helpful.

§ 41.203(a)

We acknowledge that the proposed regulatory definition of interfering subject matter is in accord with the Board’s construction of the present § 1.601(n), and the Federal Circuit has confirmed the Office’s authority to interpret the rule in that manner. The Board’s authority under the statute, however, is broader – it may, if it chooses, consider that “species” and “genus” inventions that satisfy the “one-way test” interfere. We believe that the Board should adopt a practice that would preclude the improper grant of generic claims to the second party to invent subject matter within the genus it claims.

We understand that for a variety of reasons, the Board has now chosen not to exercise the full scope of its statutory authority to conduct interferences. Yet we believe that the rules should be drafted with the recognition that it may later elect to declare interferences based on the “one-way test” for interfering subject matter. We therefore urge the Office to adopt a more flexible definition in § 41.203, for example, by providing that “The Board may determine that an interference exists if ...”

§ 41.207(a)(1)

We believe that the change proposed in this rule would be a mistake. Under current Rule 657, the evidentiary standard for establishing priority under 35 U.S.C. § 102(g) is “clear and convincing” evidence against an issued patent, and a “preponderance of the evidence” against a pending application. The proposal to place published patent applications in the “clear and convincing” category is unwarranted and, in our view, unwise.

The higher evidentiary standard used to evaluate validity flows from the presumption of validity that applies to fully examined, granted patents. Resolving questions of priority under §102(g) is part of the examination process that the PTO is charged by statute with carrying out before a patent is granted. There is no reason why patentability under only § 102(g), and not under any of the other subsections of § 102, should be determined by a higher standard for an application that has not been granted.

There is no basis in the statute, the legislative history of 35 U.S.C. § 122, or the case law for according the claims of published applications a different status than unpublished applications. The mere act of publication should not cloak a pending application in an effective presumption of validity.

§ 41.207(d)

Genentech opposes any set time limit for presuming that “abandonment” has occurred, even if the presumption is rebuttable. We appreciate that the Board wishes to develop a regular practice to address the practical problem of how to apply the “abandoned” standard of 35 U.S.C. § 102(g) in the near-absence of relevant case law. However, we believe that a “one-size-fits-all” approach would not be appropriate. The proposed presumption would prejudice some in the absence of any statutory mandate to do so.

There are many reasons why an interval of inactivity that might demonstrate the abandonment of one invention would be ordinary, expected, and appropriate for another. In biotechnology, for example, a basic invention such as a new therapeutic molecule might not show any promise for commercial development until formulation or delivery problems were resolved. Abandonment should be judged not in terms of an inflexible metric, but in terms of the activity that represents reasonable diligence in the relevant art.

More fundamentally, we believe that adopting a presumption that would affect the substantive rights of particular parties is an exercise that should not be accomplished through procedural rulemaking. While we commend the Office’s initiative with respect to this admittedly difficult issue, we believe that this should be left to the Congress.

Conclusion

We appreciate the opportunity to offer comments on the proposed changes to the Office’s procedures.

Sincerely yours,

Janet E. Hasak
Associate General Counsel – Patent Law