

Genentech, Inc.

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1 DNA Way

South San Francisco, California 94080

(650) 225-1000

Fax: (650) 952-9881

February 28, 2001

VIA FACSIMILE & E-MAIL (4 PAGES TOTAL)

The Honorable Nicholas Godici

Acting Director of the United States Patent and Trademark Office

Box Interference

Washington, DC 20231

ATTN: Interference-in-fact

Dear Sir:

The following comments are provided in response to the Federal Register Notice of December 20, 2000 (65 FR 79809) entitled "Standard for Declaring a Patent Interference".

The notice requests input on the standard used by the PTO to declare interferences. For reasons outlined below, we believe it would be appropriate and desirable for the PTO not to limit interference declarations to only those situations where there is a prima face case of "two-way unpatentability." In particular, in situations where a patent is granted on a later-filed application claiming a genus, and that genus encompasses a species claimed in an earlier-filed application, we believe it is appropriate for the PTO to resolve the inventorship question that is presented by the parties before a patent is granted on the species claimed in the earlier-filed application. Declaring interferences only after a determination that there is two-way unpatentability will create problems at an unacceptably high frequency in the biotechnology sector, and for that reason, should not be employed.

We believe that use of a two-way unpatentability test as a precondition to establishing interference proceedings would produce inequities that violate both the rule and intent of our first-to-invent patent system. Issuance of valid patents is critical to fostering respect for the Patent System. If it is perceived that the Patent and Trademark Office is not fully examining

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patents for compliance with the requirements of 35 U.S.C. 102(g), and rather is allowing certain priority and patentability issues to be sorted out through litigation in district courts, it will damage the overall respect accorded issued patents.

Interferences should be declared and conducted with the applicable patentability principles applied in the same manner as they would be applied during *ex parte* prosecution. When 35 U.S.C.102(g) prior invention issues arise, they should be dealt with in a manner that assures that the relevant priority and patentability issues are fully resolved *prior* to the issuance of the patents in question.

Arguments that conducting a thorough and complete assessment of all patentability requirements prior to the issuance of patents is overly burdensome on the PTO are neither persuasive nor a valid justification for the proposed practice. First, as a practical matter, an interference need not be immediately declared in all situations described above. Existing safeguards are sufficient to avoid frivolous requests for interference and to reduce unnecessary investments of time and resources by the PTO. For example, in relation to pending applications, the PTO will generally not declare an interference if the effective filing dates are more than six months apart. In such circumstances, the application with the earliest filing date will be issued, and then used to reject the later filed application. If a second filed application is directed to a species, and if a first filed application (filed more than six months before the second filed application) directed to a genus encompassing the species issues as a patent, then the second applicant must file evidence to show a date of invention prior to the effective filing date of the issued patent before an interference will be declared. This provides protection to the genus patentee, as only appropriate interferences will be declared. By issuing the application with the earlier effective filing date and requiring the later applicant to file evidence showing prior invention before an interference is declared, the PTO avoids the necessity of initiating an interference proceeding to determine priority of invention, and indeed, the two-way test is not implicated.

However, where a patent has been issued to a later-filed application claiming a genus encompassing a species claimed in an earlier-filed application, it is essential to resolve the inventorship question before a patent is issued on the earlier-filed application claiming the species. If the PTO permits interferences to be declared only if a two-way test is satisfied, this will not be possible. Thus, if a party having a patent or an application requests an interference and there are sufficient grounds to support initiation of the proceeding (i.e., that there is an actual question of prior invention demonstrated by a *prima facie* showing), the PTO should not hesitate to initiate the interference and resolve the inventorship questions

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Significant inequities will result from adoption of a two-way standard of unpatentability. The most glaring example concerns the issuance of an application claiming a genus before an earlier-filed application claiming only a species that is encompassed by but not obvious in view of the genus. The earlier-issuing, but later-filed application patent would be anticipated by or obvious over the earlier filed application claiming the species. Using a two-way standard, an interference will not be declared between the species application and the genus patent because the species is not obvious in view of the genus. Accordingly, the species application will issue as a patent and the validity of the genus patent will remain under a cloud. If the Patent and Trademark Office does not declare an interference to remove the cloud over the genus patent, the genus patentee is forced to resort to district court litigation for relief. If the genus patentee elects to seek no relief in district court proceedings, the public is harmed by the existence of two patents claiming the same invention.

Reexamination is not an acceptable alternative for resolving these types of patentability questions. A third party requester may only initiate a reexamination on the basis of prior art patents and printed publications. Prior invention cannot serve as the basis for establishing a substantial new question of patentability for purposes of conducting a reexamination proceeding. In addition, if the earlier filed application was fully considered by the PTO -- evidenced by the grant of the second patent notwithstanding a request to initiate an interference proceeding -- the reexamination will not be instituted under current law and practice. Even if the reexamination is commenced, the genus patentee may be able to swear behind the earlier filed application's filing date despite being unable to swear behind the 102(g) date of the first filed application. In this instance, the genus patent would survive reexamination and the outstanding question of priority would still cloud the validity of the genus patent.

Particularly in certain genus-species situations, the alternative to declaring interferences using a one-way test is litigation in district court. However, this can only be done if the holder of the dominating genus patent sues the species applicant or patentee, or the holder of the dominating patent provides a basis for the filing of a declaratory judgment action. Otherwise, the species applicant or patentee must live under the cloud of the dominating patent.

Litigation is not a reasonable alternative to an interference. While there is a substantial expense for interferences, it is small compared to the expense of infringement litigation, where numerous other issues can be raised. The Patent and Trademark Office is the appropriate place to raise issues of 102(g) prior art, not an expensive district court action (i.e., the only post-grant forum in which additional issues can be raised). This is particularly true because the complicated and relatively arcane issues relating to the interference concepts of conception, diligence, and reduction to practice are better decided in an interference proceeding before Administrative Patent Judges who deal with these issues on a daily basis, rather than in a district court proceeding before a judge or a jury.

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In summary, a two-way test would not allow interferences to be declared in some very important situations where priority between parties should be decided in the Patent and Trademark Office. The PTO should permit compliance with a one-way test for unpatentability to serve as a basis for initiating interference proceedings, subject to the comments provided above. We would be happy to provide additional views to address the practical issues raised by the PTO in administration of such a policy.

Sincerely,

GENENTECH, INC.

Sean A. Johnston

Vice President, Intellectual Property