

JAN - 7 2000

Harold Varmus, M.D.
Director
National Institutes of Health

Francis Collins, M.D.
Director
National Human Genome Research Institute
Bethesda, Maryland 20892-0148

Gentlemen:

Thank you for your cosigned letter following last month's meeting regarding PTO examination policies and their impact on the patenting of genes and gene fragments. As you are probably aware, the Revised Interim Written Description and Revised Utility Guidelines that we discussed with you at the meeting were published in the Federal Register on December 21, 1999.

The PTO appreciated receiving your comments when we first published our Interim written description guidelines. We have made every effort to be responsive to your concerns and to the concerns of other individuals and organizations who commented. Your comments were thorough and constructive and were very helpful to our staff as they revised the Interim guidelines on written description. As a result of the comments we received regarding the patentability of Expressed Sequence Tags, we revised our formerly "final" guidelines on utility.

Your letter raises two continuing concerns. First, it is your position that a claim to a polynucleotide supported solely by a theoretical characterization of the encoded protein is unlikely to possess specific utility; however, you are concerned that the PTO is likely to find the utility requirement satisfied in such a case. Second, it is your position that "comprising claims" for partial gene sequences lacking any known biological function would have overly broad scope because the written description requirement would not be satisfied; however, you are concerned that the PTO will issue patents including such claims. You attached Dr. Spiegel's letter to further explain your concerns.

With respect to the utility requirement, we are pleased that you support the three-pronged test for utility set forth in the revised guidelines. In response to concerns about whether polynucleotide sequences supported solely by a theoretical function of the encoded protein possess an acceptable utility, the PTO recognizes that the patentability of such sequences requires meticulous analysis to determine the sufficiency and disclosure of enabled utilities. Given the apparent complexities of determining utility in the biotechnology area, there are no per se rules for determining whether the utility requirement is satisfied; rather, we have established general principles, consistent with existing case law, to guide our examiners in applying the utility requirement on a case-by-case

basis. *See, e.g., In re Folkers*, 344 F.2d 970, 974, 145 U.S.P.Q. (BNA) 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties); *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d (BNA) 1436, 1441 (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement); *Brenner v. Manson*, 383 U.S. 519, 531, 148 U.S.P.Q. (BNA) 689, 694 (1966) (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics).

Notwithstanding the general principle just discussed, and without offering an opinion on any specific examples you mention in your letter, we recognize that there may be situations where membership in a family of proteins is not enough to support an inference of practical, real world benefit in currently available form. For protein families in which the individual members must be specifically activated to be useful, but the application disclosure fails to provide information explaining how to activate the protein, membership in the family may be insufficient for an inference of currently available, real world benefit, or the disclosure may fail to teach one of skill in the art how to use the invention. Depending on the specific fact pattern, the disclosure may either fail to provide a specific and substantial utility, or it may present an enablement problem. *See* MPEP § 2164.07, II ("In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph."). Protein families where the individual family members have distinct target substrates, and the protein can't be used unless the target is known, present similar issues.

NIH's second main concern is that "comprising claims" for partial gene sequences lacking any known biological function would have overly broad scope because the written description requirement would not be satisfied. In the past, our reviewing court has not approved per se "scope" rejections for overbreadth under the written description requirement. Rather, the Office has been directed to accept allegations that a generic invention has been made. *See, e.g., In re Smith*, 481 F.2d 910, 915, 178 U.S.P.Q. (BNA) 620, 624 (CCPA 1973) (broadly claimed polymers supported by tenor of specification that a generic invention has been made).

Nevertheless, some recent decisions by the Federal Circuit suggest a different result in the fact situation you describe. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d (BNA) 1895, 1905 (Fed. Cir. 1996) ("simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses"), and *Regents of the Univ. of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d (BNA) 1398, 1406 (Fed. Cir. 1997) ("generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function"). Dr. Spiegel's letter expands on your concerns and emphasizes the effect that transitional phrases might have if claims to anonymous sequences dominate later discovered full-length genes. The PTO will follow the holdings of these recent cases and apply them in pending applications as the

fact patterns warrant. We are also mindful of the enablement requirement of 35 U.S.C. 112, first paragraph, and its implications in applications wherein the description does not teach one of skill in the art how to use the full scope of the claimed invention. *See, e.g., Enzo Biochem Inc. v. Calgene Inc.*, 188 F.3d 1362, 1377, 52 U.S.P.Q.2d (BNA) 1129, 1140 (Fed. Cir. 1999) (enablement requirement was not satisfied where breadth of specification was not commensurate in scope with the claims because quantity of experimentation required would have been undue). We are exploring the impact of these recent decisions on the applications we are examining.

Thank you again for your constructive and thoughtful comments. I look forward to continued dialog on these issues as we at the PTO work toward finalizing our Guidelines.

Sincerely,

/s/

Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

cc: Jack Spiegel, Ph.D.
Director
Division of Technology Development & Transfer
National Institutes of Health