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To	Scott Chambers	From	Richard Parry
Dept./Agency	PTO	Phone #	202 720 5973
Fax #	703 305 9373	Fax #	202 720 7549
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Box 8
Commissioner of Patents and Trademarks
Patent and Trademark Office
Washington, DC 20231

Attention: Scott A. Chambers
Associate Solicitor

Comments on Interim Guidelines for the Written Description Requirement for Patent Applications

The following comments are presented by Richard M. Parry and M. Howard Silverstien represent the views of the Agricultural Research Service, U.S. Department of Agriculture.

The efforts of the PTO to provide clear, consistent guidelines for the examination of patent applications is to be commended. The guidelines presented represent a step in the right direction for the clarification of the written description requirement.

I. For the most part, the interim guidelines are clearly stated, and the criteria appear compatible with established procedures. Part A requires, for example, a complete review of the application in order to determine what the invention is and the level of predictability in the art.

Part B, on the other hand, is confusing. The guidelines for determining what the claim as a whole covers are unclear and do not appear to be consistently applied over the range of examples given.

For example, when considering the claim "A gene comprising SEQ ID NO: 1", the claim is considered in separate parts: the preamble, "A gene", the transitional phrase, "comprising", and the body of the claim, "SEQ ID NO: 1". The transitional phrase "comprising" is open-ended and covers what is specifically claimed as well as additional unspecified subject matter. The preamble term "gene...implies a specific structure" and "implicitly" recites other structures such as promoters, enhancers, coding regions, etc. These structures must be sufficiently described in the specification in order for an applicant to demonstrate possession of the invention. In addition, "gene" is viewed as generic while "SEQ ID NO: 1" is a species in a combination/subcombination format. A written description of only the subcombination would not put one in possession of the combination if the transitional phrase "comprising" is used in the claim, thus implying additional structures which are present and must also be described. These guidelines also apply to other structures such as mRNA and cDNA.

On the other hand, there is no such implication attributed to the preamble term "DNA" in a claim reciting "A DNA comprising SEQ ID NO: 1". "Nucleic acid" is considered a generic term and "does not typically present a written description problem because one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus." This may be true if limited to the specific recited sequence, but the open-ended transitional phrase includes unspecified subject matter. One of skill in the art indeed knows the structures of the various nucleotides, but it doesn't necessarily follow that one can readily envision additional unspecified nucleotides based only on one recited fragment. Since genes, cDNAs and mRNAs are all made up of DNA or RNA, claims directed to DNA or RNA could conceivably encompass such genes, cDNAs or mRNAs. Therefore, it is inconsistent for use of the terms "gene", "cDNA", "mRNA" and the like to require a more detailed written description in order to demonstrate possession of a given invention than that required for

the terms "DNA" or "RNA", given the use of the transitional term "comprising".

II. DNA and RNA are chemical compounds, specifically organic compounds, as opposed to a mechanical structures. Guidelines which conventionally apply to such compounds should therefore be applicable. In order to claim possible variations in the basic structure of a compound (i.e. the genus), applicants may include variables such as defined R groups, thus clearly identifying what the claim as a whole covers. This kind of limitation, in the claim itself and/or in the written description, precludes the inclusion of an inordinate amount of additional "unspecified" material. Analogously, inventions directed to DNA or RNA may also describe variations which may be present in the sequences in order to clearly convey what the claims cover.

III. Scientists, especially those in the public sector, are concerned that they may be precluded from conducting research in some instances because of broad patent protection on genetic materials. In particular, express sequence tags (ESTs) have become very controversial, especially since they have been deemed patentable subject matter. Consider the following scenario:

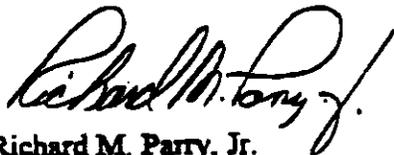
- A. Company A, a large seed company, in collaboration with Company B, a company which specializes in genome research, produces ESTs from maize.
- B. The two companies obtain patents on one or more of the ESTs.
- C. Independently, agricultural scientists, looking for a particular gene which controls an important trait in maize (e.g. virus resistance, heat tolerance, etc.), find the gene, sequence it and publish and/or patent it.
- D. The disclosed gene encompasses at least one of the sequences of the patented ESTs owned by Companies A and B.

E. The large seed company's patent could then dominate, making it difficult, if not impossible, for the gene to be successfully utilized by the inventors who actually discovered it. Commercialization of the gene would be difficult, if not impossible.

Should a claim to an EST with no known function (except for the somewhat hypothetical situations deemed sufficient by the PTO) be allowed to dominate such an important invention? Clearly, the inventors of the ESTs were not in possession of the entire gene. Yet, the guidelines appear to permit such a situation to occur.

Although other criteria are also considered when examining claims, there is some interrelationship between the written description of what a claim covers and the scope of that claim. Thus a clear description of what the invention actually covers is very important when genetic materials are the subject matter. Perhaps the use of open-ended transitional language without some accompanying limitations which clearly define the limits of nucleic acid sequences is inappropriate.

Thank you for the opportunity to express the concerns of the ARS.



Richard M. Parry, Jr.
Assistant Administrator
Office of Technology Transfer
Agricultural Research Service
U.S. Department of Agriculture



M. Howard Silverstein
Deputy Assistant General
Counsel for Patents
U.S. Department of Agriculture