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EST'S AND PARTIAL  
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# EST's And Partial Sequences: Repercussions For The Biotech Client

(A PANEL DISCUSSION  
AT BIOGEN, INC. —  
CAMBRIDGE, MA)

REPORTED ON BY JAMES A. COBURN

On May 22, 1997, the Boston Patent Law Association ("BPLA") held a panel discussion entitled "EST's and Partial Sequences: Repercussions for the Biotech Client," at the offices of Biogen, Inc. (Cambridge, MA). Approximately 100 people attended the two hour meeting, which was moderated by Leslie Levine (Biogen), with panelists Beth Arnold (Foley, Hoag & Elliot), Scott Brown (Genetics Institute, Inc.) and P. Louis Myers (Lahive & Cockfield). Paul Clark (Clark & Elbing), although scheduled as a panelist, was unable to attend.

Based upon comments made by Deputy Commissioner Lawrence Goffney in February at an American Association for the Advancement of Science ("AAAS") meeting in Seattle, it appears that the United States Patent and Trademark Office ("PTO") may, at some time in the near future, allow patent claims to expressed sequence tags ("EST's") and partial DNA sequences, even though the applicant may know little to nothing about the sequence's biological activity. The discussion, therefore, centered on key issues such as prosecution strategy, possible PTO policy changes, the effect on interference procedure, the impact of a partial sequence claim on the subsequent patentability of the complete gene and/or method of use claims, licensing strategies, as well as various infringement scenarios.

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The main concern of those in attendance, however, clearly centered on the issues of utility and enablement of a claimed partial sequence (with limited knowledge of the sequence's biological function) with regard to 35 U.S.C. §§ 101 and 112, first paragraph. In the absence of a sequence's known biological function, it appears that the PTO now considers the use of EST's as probes for unknown genes to be a practical utility. Many at the meeting, however, expressed concerns that generically stating the use of an EST as a probe provides little to no practical (real world) value to the research community, which in turn creates a deficiency under Section 112, first paragraph, since a specification cannot enable one skilled in the art to use an invention that is not useful.

Several of the attendees recently spoke with key officials at the PTO and offered the following insightful remarks:

- There are approximately 500,000 EST/partial sequences presently pending at the PTO (presumably, to be restricted 10 to a case);
- A new PTO position is going to be created (Jasmine Chambers was mentioned) that will review every Official Action pertaining to an application containing EST's to ensure that the guidelines of Sections 101 and 112, first paragraph are being correctly applied;
- It appears as though the PTO will allow EST claims with broad "comprising" language;
- File a provisional application containing several (thousand) partial sequences; this process effects a priority date for all of the sequences, while allowing researchers some additional time to discover the sequences' true function (aside from asserting their use as a probe); and

- Based upon the NIH's vocal opposition to the issue of allowing patent claims to EST's (See Jack Spiegel's letter to Lawrence Goffney dated March 21, 1997), the NIH is likely to challenge the first EST patent which reads upon one of its genes.

The issues surrounding the above discussion are plentiful and complex. The repercussions of EST and partial sequence patenting are likely to be felt at the PTO, into the courts and, ultimately, in the biotech community for several years to come. As the meeting wound down, the general consensus on riding out the storm was (i) file early and often, on anything and everything; (ii) draft claims as broadly as possible; (iii) be creative in asserting the most reasonable utility available at the time of filing; and (iv) make good use of provisional application practice — it buys time. For more information, or to request a videotape of the panel discussion, please contact Leslie Levine at (617) 679-2810. 

James A. Coburn, who attended the meeting, is President of **HARBOR CONSULTING Intellectual Property Services** - DNA & Amino Acid Sequence Listings, and Publisher of **BioChem-AgPharma News™** by facsimile, a weekly facsimile news service dedicated to circulating the latest Intellectual Property, FDA, legal and business news as it relates to the biotech, chemical, agricultural and pharmaceutical industries. Mr. Coburn is presently preparing to sit for the 1997 Patent Bar.

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