Training Module for Chapter 24 of the MPEP

(Revised August 16, 2018)

Summary

Chapter 24: Biotechnology

NOTE: The provisions of Chapter 24 have <u>not</u> been changed by the AIA.

Section 2402 – The Deposit Rule

- Section 112 requires every patent to contain a written description of the invention that is sufficient to enable a person skilled in the art to make and use the invention.
- When in invention involves biological material and words alone cannot sufficiently describe how to make and use the invention, access to the biological material may be necessary for the satisfaction of the statutory requirement for patentability.

IN SUCH CASES, AN APPLICANT MAY SUPPLEMENT A WRITTEN APPLICATION WITH THE DEPOSIT OF BOILOGICAL MATERIAL.

• Although the USPTO strongly encourage applicants to deposit biological material before or simultaneously with the filing of an application, the deposit may be made at any time during the pendency of the application.

NOTE: If the biological material is readily available or easy to make, no deposit is required.

Section 2422 – Nucleotide and/or Amino Acid Sequence Disclosures to Patent Applications

- Rules related to sequence listing were developed to combat the problems associated with the lack of uniformity in the submission of sequence data to the USPTO and the impracticality of searching and examining sequences submitted in paper format.
- Thus, all applicants which contain disclosure of nucleotide or amino acid sequences must conform to these rules.
- A significant aspect of these rules requires the sequence be disclosed using the symbols and format provided by the rules.
- The sequences may be submitted on both paper and CD format. However, if paper format is used, a copy of the sequence listing *must* also be submitted in computer readable form.
- If an applicant fails to properly disclose the sequence listing or fails to submit a computer readable format, a Notice to Comply will be issued.

Selected Questions and Answers for Chapter 24 - None

In-Depth Review of Chapter 24

Please click on the link, below, to bring up a special version of Chapter 24 in the MPEP that has been prepared exclusively by **PassPatentBar** to complete your review of this chapter. It is recommended that you quickly scan through most of this chapter while reading only those sections, about 10% of the total, that are highlighted-in-yellow. When you are finished with this review, please return here by using the return arrow at the top-left on your screen.

Chapter 24 MPEP