The precedent set by the Supreme Court in Diamond v. Chakrabarty (447 U.S. 303 (1980)) held that "anything under the sun that is made by man" is patentable under 35 U.S.C. § 101. This standard allowed for the patenting of even mathematical formulas applied in practical processes, such as curing rubber, and genetically modified organisms. However, the rise of attempts to patent abstract ideas and business methods has prompted the development of more nuanced case law regarding patent eligibility.

Two pivotal cases, Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012) and Alice Corp. v. CLS Bank International, have shaped the current two-step subject matter eligibility test detailed in MPEP § 2106. Despite this standardized test, its application by examiners varies. Some examiners emphasize the machine-or-transformation test, others consider whether the process can be performed mentally with simple tools like pen and paper, while another group focuses on problem-solving or the presence of an inventive concept. Therefore, response strategies must be tailored to these differing interpretations.

Moreover, MPEP § 2106.07 presents a challenge by stipulating that even if an independent claim is patent-eligible, a dependent claim may not be, if it introduces a judicial exception without integrating it or adding significant limitations. Ongoing developments in this area will be closely monitored to provide updated guidance on response strategies.