Life Sciences Due Diligence and the Interplay with Recent Prosecution Timing Changes at the USPTO

September 29, 2025 Jeffrey Morton

PRACTICES Intellectual Property, Patent Prosecution and Counseling, Life Sciences, Biotechnology

Most life sciences transactions result in intellectual property (IP) due diligence being carried out on underlying IP assets that are often central to the transaction. Typically, this includes a focus on patent due diligence to determine whether key patent assets are valid and enforceable. For many life sciences companies, and particularly for early-stage companies, patent prosecution is proceeding at the same time as active due diligence. Accordingly, effective due diligence is often characterized by taking “snapshots” of a moving target, the moving target being the ongoing patent prosecution.

Recently, there have been a number of changes in patent practice in front of the United States Patent and Trademark Office (USPTO) that have impacted prosecution timing. These changes have the potential to impact due diligence of patent matters that are under active prosecution.

A common feature of life sciences patent prosecution is the interplay between obtaining the issuance of valuable patents while simultaneously ensuring that prosecution continues through the filing of continuing applications. Continued prosecution allows patent owners to refine their long-term patent strategy, often through the prosecution of broader patents. As of Jan. 19, 2025, in an effort to reduce the growing backlog of continuing applications and promote efficient prosecution, the USPTO began requiring a Continuing Application Fee (CAF) for certain continuing applications filed six or more years after their Earliest Benefit Date (EBD) (the EBD is the earliest date under which priority can be claimed).

Patent applicants often file what are commonly known as “no fee” continuing applications, which allow for the deferral of fees until a response is required to a Notice to File Missing Parts. This strategy provides patent applicants with a significant time delay (e.g., 7 months) in which they can refine their patent claim strategy.

However, the changes implemented at the USPTO have created a potential trap for filers of “no fee” continuing applications. If a continuing application requiring a CAF is filed without the necessary fee, the USPTO will not acknowledge priority claims to applications filed six or more years prior. This means that the filing receipt will exclude such priority claims. Of note, the USPTO will not send a notification to applicants informing them about the deletion of the priority claim. As a result, there is no explicit communication to which applicants can respond to correct omitted priority claims. All of this is important for applicants, such as those in the life sciences industry, that rely on continuing application procedures, and oftentimes have continuing applications filed many years after their EBD.

Related to the above changes in continuation practice, as of May 13, 2025, the USPTO began accelerating the Issue Dates for patents. Under these changes, the time between Issue Notification and Issue Date was reduced to approximately two (2) weeks. By shortening the wait time between the Issue Notification and the Issue Date, patent applicants filing continuation applications need to ensure that such applications, with well-reasoned claims, are filed before the parent patent issues.

Patent Prosecution Acceleration Changes

Another common feature of life sciences prosecution is the use of expedited prosecution for certain patent applications.

Effective July 10, 2025, the USPTO discontinued the Accelerated Examination program for utility applications. The Accelerated Examination program, which was initiated in 2006, was a relatively popular program as it was one of the few options for patent applicants to receive expedited examination. Reasoning for the decision to discontinue the Accelerated Examination program was multi-faceted and included: the need to reduce overall first-action pendency at the USPTO; the current low usage of the Accelerated Examination program and comparatively, the popularity of the Track One program that was initiated in 2011; and the inconvenience to practitioners and the USPTO of retaining a seemingly redundant program with its own special handling procedures.

Patent applicants that wish to accelerate patent examination in the United States should focus on the Track One program, which is already popular among many applicants, particularly those in the life sciences industry. Track One provides the ability to advance a utility patent application out of turn, regardless of subject matter, by paying a fee and without an applicant having to satisfy the more burdensome requirements of the Accelerated Examination program, such as performing a pre-examination search and supplying an examination support document.

The interplay between expediting certain patent applications and managing the rapid issuance and subsequent continuing application strategy is central to the development of a coherent and strong patent portfolio. Not paying attention to these new changes could have significant negative effects in a life sciences patent due diligence.