Review of FDA's 2021 Drug Approvals – Small Molecules Dominate



The FDA's Center for Drug Evaluation and Research (CDER) approved 50 new drugs and biological products in 2021 (not including the vaccines, cellular and gene therapy products, or other products approved in 2021 by the Center for Biologics Evaluation and Research). As in past years, small molecule drug approvals dominated the list.

Of the 50 approved new drugs and biological products, 33 were small molecule drugs and 17 were monoclonal antibodies and other big molecules drugs. A new ADC (antibody drug conjugate) was approved, Tivdak®, and a bispecific antibody was also approved, Rybrevant®. Notably, a small interfering RNA drug was approved, Leqvio®, for the treatment of atherosclerotic cardiovascular disease.

As small and big molecule drugs enter the clinic, Goodwin's patent attorneys focus on securing not only composition of matter patent protection, but additional patent protection derived from clinical data. Learn more about additional patent protection secured from the clinic in **Goodwin's Patent Savvy Executive video**.

Each new drug and biological product can be found in the FDA's **Orange Book** or the FDA's **Purple Book**. To learn more about the Orange Book and how to determine patent terms on approved drugs, visit **Goodwin's Patent Savvy Executive video**.

See the full list **here**.

When does my patent expire?



To determine when your (or your competitor's) patent expires, first identify the correct filing date of the patent application. A U.S. utility patent (filed on or after

June 8, 1995) expires 20 years from the earliest filing date of the patent. If the patent claims priority to an earlier patent application, then the 20 year term starts from the filing date of the earlier patent application. (Note, some earlier patent applications are excluded from this consideration and do not impact the patent term). You can determine if your patent claims priority to an earlier patent application by looking at the first page of the patent for a subsection titled "Related U.S. Application Data." Sometimes this information is also found in the first paragraph of the specification of the patent. If your patent claims priority to one or more earlier-filed patent applications, those patent applications will be listed by their application number and filing date in this subsection. Application numbers can be in the format of an international patent application (having the application serial number format of PCT/XXYEAR/######) or in the format of a U.S. patent application (having the application number format of 01/###,### through 16/###,###). Identify the earliest filing date from these patent applications, and the patent term expires 20 years from this date.

However, if the "Related U.S. Application Data" lists one or more provisional U.S. patent applications (having the application serial number format of 60/###,### through 63/###,###), then these filing dates are not used to calculate patent term. If only provisional U.S. patent applications are listed in the "Related U.S. Application Data" subsection, or if this subsection is missing from the front of the patent, then the filing date for purposes of calculating patent term is the filing date listed on the left front page of the patent, indicated as "Filed:" In this case, the patent term expires 20 years from the filing date on the front page of the patent.

In some cases, a patent may be extended beyond its 20 year term. For example, some patents are awarded a patent term adjustment (PTA) by the United States Patent Office. If a patent is awarded PTA, this is typically listed on the front page of the patent. For example, the front of the patent may state, "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 246 days." If the patent has this award, add the number of days of PTA to the patent term. Additionally, some patents are awarded a patent term extension (PTE) by the United States Patent Office. If a patent is awarded a PTE, a Patent Term Extension Certificate is filed in the file history of the patent. The file history of the patent can be found at **https://portal.uspto.gov/pair/PublicPair**. If the patent has been awarded a PTE, add the number of days of PTE to the term of the patent in addition to any PTA award.

Finally, a patent term may be shortened. In these cases, the front of a patent may (or may not) state that "This patent is subject to a disclaimer." In this case, the patentee has surrendered any patent term (including any PTA) beyond the expiration date of another patent. Identifying this patent or application can be found by reviewing the file history of the patent at **https://portal.uspto.gov/pair/PublicPair**. We recommend you contact your Goodwin life sciences or patent lawyer for a determination of how this disclaimer impacts patent term.