

Axitinib: Patenting Innovation for Patients' Benefit

Below we explore the tangible and essential benefits that patents bring to patients. Opponents of innovation have falsely claimed that, on average, products are covered by hundreds of patents that delay generic market entry. The truth directly contradicts this false "patent thicket" narrative. For example, only four key patents are listed for axitinib in the U.S. Orange Book.

CASE STUDY: Axitinib

Axitinib is prescribed to treat advanced kidney cancer as the first treatment option when combined with pembrolizumab or avelumab or on its own if other treatments have not worked. It works by blocking certain proteins in the body, tyrosine kinases, that are involved in the growth and spread of cancer cells. By doing this, axitinib helps to slow down or stop the growth of cancer cells. The U.S. Food & Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) lists the following four patents for axitinib.*

Patent No. US 6,534,524

This patent covers axitinib, a tyrosine kinase inhibitor that is the active ingredient in our marketed drug.

Through its targeted therapy, axitinib has improved treatment outcomes and expanded treatment options for patients with advanced kidney cancer. The availability of axitinib has brought hope and extended survival for patients battling this challenging disease.



Patent No. US 8,791,140

This patent covers the specific, most stable, solid form of axitinib.

This discovery describes a crystal form that is more stable and has better industrial manufacturability. These characteristics increase the stability of the commercial form of the product and provide more cost-effective manufacturing.

Patent No. US 10,570,202

This patent covers treating patients with the combination of axitinib and pembrolizumab.

This discovery has brought substantial benefits to patients, transforming the treatment landscape for advanced kidney cancer. Through this innovative combination, which is the result of collaboration between two innovative pharmaceutical companies and is now a first-line therapy, patients have gained access to a tailored treatment strategy, providing them with improved chances of disease control and prolonged survival.



Patent No. US 10,869,924

This patent covers treating patients with the combination of axitinib and avelumab.

The combination of axitinib and avelumab offers several benefits for patients, including delayed disease progression and expanded treatment options.

*The Orange Book contains patents "for which a claim of patent infringement could reasonably be asserted" against a company seeking to make a generic version of the medicine (21 U.S.C. 355(b)(1)).

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