Why C4IP Opposes the Affordable Prescriptions for Patients Act (S. 1041)

The Affordable Prescriptions for Patients Act would limit the number of patents that a drug manufacturer could defend in court, and particularly restrict companies from defending follow-on patents filed more than four years after a drug initially secured FDA approval.

The Myth of "Patent Thicketing"

Lawmakers want to combat the alleged practice of "patent thicketing," in which drug companies supposedly file numerous patents on various components of their medicines to extend their market exclusivity and prevent the entry of generic and biosimilar competitors.

However, the bill is based on myths and misunderstandings about how patents work. Weakening IP protections for medical innovators would undermine the incentives that have made America the world leader in drug development.

What the Data Actually Shows

A comprehensive study conducted by the U.S. Patent and Trademark Office (USPTO) at the request of Senator Thom Tillis thoroughly debunked the myth of patent thickets.

Key takeaways include:

- Filing patents on different components of a single product is common across many high-tech industries, from automobiles to consumer electronics.
    - For instance, Apple filed around 200 patents for the first iPhone. Each one protected unique innovations in hardware, design, user interface, and much more.
- Simply counting the number of patents on a drug does not provide a clear picture of the competitive environment or how long the product's exclusivity will actually last.
- Follow-on patents do not "extend" earlier patents or block the introduction of biosimilars.

How the Bill Will Harm the Innovation Ecosystem – And Patients

By limiting inventors' ability to protect various novel components of medicines — and also conditioning patent enforceability on the date a drug was approved — the bill would discourage investment into improved versions of medicines. For instance, an updated drug might include a time-release function that reduces the chance of an adverse reaction. These innovations can translate into better patient health outcomes by making treatments safer, more effective, or easier to use. Discouraging their development hurts patients.

The bill would also disadvantage American drug innovators by giving biosimilar manufacturers — many of which are foreign — an advantage in patent infringement lawsuits.

Bottom Line

S. 1041 would arbitrarily limit the enforceability of certain patents — not due to any alleged defect with the patents themselves, but simply due to the quantity of other patents owned by a litigant and the date those patents were filed. While this bill only targets drug patents, it would set a worrying precedent for innovators and investors in other industries who will surely perceive the potential future risk to their own inventions.