Statement of

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Statement for the Record for "Medicine and IP: Balancing Innovation and Access" Subcommittee of Courts, Intellectual Property, Artificial Intelligence, and the Internet Hearing

Chairman Issa, Ranking Member Johnson, and Members of the Subcommittee, thank you for the opportunity to submit this statement for the record for the hearing entitled *"Medicine and Intellectual Property: Balancing Innovation and Access."*

The United States remains the global leader in medical innovation. American research and development have produced life-saving treatments, extended life expectancy, improved quality of life for millions of patients, and driven economic growth. Our intellectual property system has played a critical role in fostering these breakthroughs. However, a patent system that rewards true innovation must also promote competition and ensure patients can access affordable medicines.

Today, one of the most significant barriers to lower drug costs is the growing use of pharmaceutical patent thickets. While patents are intended to incentivize innovation, they are increasingly being used to extend monopolies beyond the life of the original invention. Pharmaceutical manufacturers routinely obtain dozens of additional patents on existing products, often covering minor modifications rather than meaningful scientific advances. When comparing the U.S. patent process to other countries, there are on average nine times more patents asserted against biosimilars compared to Canada, and twelve times more patents asserted compared to the U.K. Both Canada and the U.K have been found to have biosimilars enter the market quicker than in the U.S. While the U.S. leads the world in medical innovation, we need a patent system that can make those innovations accessible to patients.

Patent thickets function as legal fortresses that shield brand-name drugs from competition. By surrounding a single product with dozens of overlapping patents, manufacturers dramatically increase the cost and complexity of litigation for generic and biosimilar companies seeking to enter the market. Rather than competing on the merits of innovation, smaller competitors are often forced to spend years and millions of dollars navigating duplicative patent claims before they can bring lower-cost alternatives to market. Academic research has found these patent thickets can delay biosimilar entry by two to four years by making the challenge process prohibitively expensive, regardless of the strength of the underlying patents.

My legislation, H.R. 3269, the *Eliminating Thickets to Increase Competition (ETHIC) Act*, addresses this imbalance while preserving the incentives that drive American innovation. The bill would prevent brand-name manufacturers from weaponizing duplicative patents against biosimilar competitors by allowing only one patent per patent family to be asserted in litigation. This targeted reform would reduce abusive litigation tactics without limiting legitimate patent protections for genuine discoveries.

Let me be clear: the ETHIC Act does not prevent manufacturers from seeking patents on novel inventions, breakthrough therapies, or meaningful improvements to existing treatments. Companies would remain free to pursue and protect legitimate innovations. The legislation simply addresses the practice of obtaining and asserting multiple duplicative patents covering the same underlying invention in order to delay competition. By distinguishing true innovation from strategic patent accumulation, the ETHIC Act strengthens both the integrity of our patent system and the competitiveness of our pharmaceutical marketplace.

A clear example of this problem can be seen with the FDA-approved migraine drug Symbravo, produced by Axsome Therapeutics. The drug is currently associated with 94 patents scheduled to expire in 2036. However, only five of those patents represent distinct, incremental innovations tied to separate patent families. The remaining 89 patents are duplicative and derive from those same underlying inventions. Oftentimes, the molecular content of the drug is exactly the same in each of these duplicative patents, making the duplicative patents lack novelty and innovation.

Generic manufacturer Apotex sought to enter the market and provide patients with a more affordable alternative. Since September 2025, however, Apotex has faced litigation involving 75 separate patents asserted by Axsome. The sheer volume of litigation creates an enormous financial burden and threatens the viability of smaller competitors before they ever reach the marketplace. Under the ETHIC Act, litigation could be narrowed to the five distinct patent families at issue, allowing courts to focus on the merits of genuine innovations rather than forcing competitors to challenge dozens of duplicative claims. Such a reform would provide companies a meaningful opportunity to compete and would ultimately benefit patients through increased competition and lower prices.

The consequences of patent thickets extend far beyond individual companies. Delayed generic and biosimilar competition keeps prices elevated for patients, employers, insurers, and taxpayers. Studies consistently show the introduction of generic and biosimilar competitors lowers drug prices and generates substantial savings throughout the healthcare system. On average, generic drugs are 75 percent cheaper than brand-name drugs. Yet patent thickets continue to postpone that competition, allowing monopoly pricing to persist long after the original innovation has been rewarded.

These practices are fundamentally anti-competitive and undermine the balance our intellectual property laws were designed to achieve. The patent system should reward scientific discovery, not procedural gamesmanship. It should encourage innovation while ensuring that patients benefit from competition once legitimate patent protections have expired.

Congress has a responsibility to protect both innovation and access. The ETHIC Act strikes that balance by preserving incentives for research and development while preventing the abuse of duplicative patents that unnecessarily delay competition. By closing this loophole, we can lower prescription drug costs, expand access to affordable medicines, strengthen market competition, and maintain America's position as the world leader in pharmaceutical innovation.

Chairman Issa, Ranking Member Johnson and Members of the Committee, I encourage you to support my ETHIC Act and mark it up. This important legislation will increase access to lifesaving drugs and stop brand-name manufacturers from gaming the patent system to push out generic and biosimilar drugs from the market.

Thank you for the opportunity to submit this statement for the record.