WRITTEN TESTIMONY OF

Rachel Goode

Senior Vice President, Head of Legal and Intellectual Property, Biopharmaceuticals

Fresenius Kabi

BEFORE THE

COMMITTEE ON THE JUDICIARY

Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet

U.S. House of Representatives

Medicines and IP: Balancing Innovation and Access
June 4, 2026

Chairman Issa, Ranking Member Johnson, and Distinguished Members of the Subcommittee:

Good morning and thank you for the opportunity to provide testimony on Medicines and IP: Balancing Innovation and Access. My name is Rachel Goode, and I am the Senior Vice President, Head of Legal and Intellectual Property for the biopharmaceuticals business of Fresenius Kabi, a global healthcare company dedicated to bringing high-quality, affordable generic drugs and biosimilars to patients with critical and chronic conditions. Fresenius Kabi employs over 4,000 people in the United States and has invested over $1 billion in US-based manufacturing, with key domestic manufacturing, research and development, and distribution centers in Illinois, Nevada, North and South Carolina, New York, Pennsylvania, and Wisconsin.

On behalf of Fresenius Kabi, we urge Congress to rebalance the current system by enacting the following legislation:

- **H.R. 3269, the ETHIC Act**, which will prevent branded drug companies from asserting multiple overlapping patents that delay generic and biosimilar competition; and

- **H.R. 6485, the Skinny Labels, Big Savings Act**, which will prevent branded drug companies from asserting patents on limited uses to block generics and biosimilars approved for unpatented indications.

Separately, we urge Congress to protect the critical *inter partes* review ("IPR") process that enables generic and biosimilar companies to challenge patents that should not have issued. To be clear, Fresenius Kabi fully supports innovation and is pro-patent, but believes Congress must act to close gaming loopholes in the patent system, allow the United States to remain as the innovation center of the world, and enable broader access to medicine.

H.R. 3269, the Eliminating Thickets to Increase Competition (ETHIC) Act

Beginning with the ETHIC Act, this legislation is critical to addressing the barriers created by patent thickets. In 2022, I co-authored an article titled, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, in which we studied the patent assertions against the same biosimilar drugs across three countries.[1] Our study found "that significantly more patents cover biologic drugs in the USA than they do in the UK and Canada," and consequently, significantly more patents are asserted against biosimilar companies in the USA than those

[1] *See* Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J. Law Biosci. 1-24 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9439849/pdf/lsac022.pdf

countries.[2] In our study of 30 biosimilars, "[w]e found that 377 patents were asserted against biosimilars in the USA, 50 in the UK, and 24 in Canada."[3]

The reason significantly more patents issue for biologic drugs in the USA is not due to innovation—it is due to patent thickets. As I explained in my paper, "[p]atent thickets are dense webs of often overlapping patents" that typically "cover the same or very similar subject matter."[4] A prime example is the U.S. patent portfolio for the biologic Humira. In our study, we found that approximately 80% of Humira's U.S. patent portfolio—which spans roughly 73 patents—consisted of duplicative patents.[5] In contrast, Humira's European patent portfolio "was dramatically smaller and was comprised of only eight non-duplicative patents."[6]

Patent thickets are a unique problem in the United States due to the availability of terminal disclaimers. Under current U.S. law, "patent owners are permitted to own patents that are obvious as compared to one of its earlier patents so long as the owner agrees to a terminal disclaimer."[7] Patent owners are thus unbounded in the number of patents they can obtain for obvious variants of the same invention. This is problematic for many reasons, but most importantly, terminal disclaimers result in more duplicative patents which result in higher drug costs for patients. We found that in the USA, "there is an average delay of 34 months between FDA approval and biosimilar launch," while the average delay in Canada is merely 7.4 months, and in the United Kingdom, it is a mere 4.7 months.[8] Biosimilars thus "enter the UK and Canadian markets more quickly than they do in the USA," with an average of a "4 times longer delayed launch of biosimilars in the USA compared to Canada and 7 times longer compared to the UK."[9]

The ETHIC Act will prevent branded drug companies from asserting multiple duplicative patents in patent litigation, allowing generic and biosimilar companies to efficiently challenge low quality patents and bring lower-cost drugs to the market sooner. While terminal disclaimers will still be available to patent owners, the ETHIC Act will make one important change: it will prevent patent owners from weaponizing terminal disclaimers to delay or block competition. The ETHIC Act also incentivizes innovation because it allows brand companies to assert, in full, non-duplicative patents that represent true innovation. It is imperative that Congress reform terminal disclaimer practice and the Ethic Act is a powerful opportunity for Congress to do so.

---

[2] *Id.* at 23.

[3] *Id.* at 23;*see also id.* at 8-10.

[4] *Id.* at 2.

[5] *Id.*at 18-19.

[6] *Id.* at 4.

[7] *Id.* at 17.

[8] *Id.* at 14-16.

[9] *Id.* at Abstract, 16.

H.R. 6485, Skinny Labels, Big Savings Act

Another important piece of legislation is the Skinny Labels, Big Savings Act. The Skinny Labels, Big Savings Act addresses a separate form of patent abuse in the pharmaceutical industry: branded drug companies asserting method-of-use patents against generics and biosimilars that are approved solely for unpatented indications.

In simple terms, if a branded drug that is no longer patented itself is approved for multiple indications, only some of which are patented, the generic company can carve out the patented uses and seek approval of only unpatented uses. Through this skinny label pathway, the Supreme Court recognized that "one patented use will not foreclose marketing a generic drug for other unpatented ones."[10] Yet two recent decisions from the U.S. Court of Appeals for the Federal Circuit have significantly undermined the skinny label mechanism.

In these two cases, the Federal Circuit has held that skinny labels can serve as evidence that generic companies intended to induce doctors to infringe the brand's patented method that the generic carved out from its label. In *GSK v. Teva*, the Federal Circuit held that Teva induced infringement of an indication that it had carved out from its label, holding Teva's FDA-approved label was not skinny enough and relying on anodyne statements indicating Teva's generic drug was equivalent to the brand.[11] In *Amarin v. Hikma*, the Federal Circuit reversed a motion to dismiss patent infringement allegations against a skinny-labeled generic drug, again relying on a skinny label that carved out the claimed indication and public statements characterizing Hikma's product as a generic version of the brand.[12] As former Representative Henry Waxman explained, these cases "threaten[] to decimate the compromise at the heart of the Hatch-Waxman Act."[13]

The Supreme Court granted certiorari in the *Amarin v. Hikma* case and a decision is expected soon, but regardless of the outcome of that case, Congress must act to protect the Hatch-Waxman framework. The Skinny Labels, Big Savings Act will provide "a statutory safe harbor from patent infringement claims for generic or biosimilar manufacturers that seek or obtain approval for skinny labels of their drugs." H.R. 6845 thus promotes the Hatch-Waxman Act's longstanding skinny label provision. This is critically important because the skinny label pathway enables generic drugs to reach the market sooner, saving patients in the USA billions. For example, for the drug Crestor alone, the skinny label provision allowed generics to enter the

[10] *Caraco Pharm Labs v. Novo Nordisk*, 132 S. Ct. 1670, 1682 (2012).

[11] *GlaxoSmithKline LLC v. Teva Pharms USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021).

[12] *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.th 1370 (Fed. Cir. 2024).

[13] Brief of *Amicus Curiae* Former Congressman Henry A. Waxman in Support of Petitioners, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889 (Feb. 25, 2026), Waxman Amicus Brief.

market 6 years sooner, saving patients more than $8.4 billion in 2019 alone.[14] We urge Congress to enact the Skinny Labels, Big Savings Act to protect the generic drug approval pathway.

Protecting Biosimilar and Generic Companies' Access to IPR

The last topic we'd like to address today is IPRs. Congress created IPR as part of the AIA to provide an efficient and cost-effective forum to "weed out bad patent claims efficiently,"[15] yet recently proposed rulemaking has materially undermined that goal. For example, the Patent Office has modified its practices to significantly increase the frequency of discretionary denials. Often by citing a new principle rooted in "settled expectations," the Director has discretionarily denied 385 petitions between October 2025 and April 2026 alone.[16] These actions have chilled IPRs in the pharmaceutical industry, with significantly fewer IPRs being filed each month.[17]

IPRs are a critical pathway for generic and biosimilars to challenge weak patents. Given the prevalence of patent thickets and other patent abuses, it is imperative that generic and biosimilar companies have a means to efficiently challenge patents. Numerous patents on branded drugs have been invalidated through IPR.[18] Yet recent attempts by generic and biosimilar companies have failed due to the Patent Office's new practices. The Patent Office's recent approach to IPRs is unworkable in the pharmaceutical context—where, due to development timelines and regulatory exclusivities, generic and biosimilar companies often seek to challenge patents that have been in force for more than six years, long after such "settled expectations" have been established.

For these reasons, we ask Congress to take action to ensure IPR remains a viable pathway for generic and biosimilar companies to challenge bad patents.

Thank you again for the opportunity to present testimony on this important issue, and I look forward to your questions.

---

[14] Brief for The Association for Accessible Medicines as *Amicus Curiae* Supporting Petitioners, *Hikma Pharms USA Inc. v. Amarin Pharma, Inc.*, No. 24-889, at 28 (Feb. 25, 2026), AAM Amicus Brief.

[15] H.R. Rep. No. 112-98, pt. 1, at 40 (2011).

[16] PTAB Trial Statistics (April 2026), at 6, https://www.uspto.gov/sites/default/files/documents/April_2026_Trial_Statistics.pdf

[17] Dennis Crouch, Inter Partes Review in 2026, https://patentlyo.com/patent/2026/05/inter-partes-review-in-2026.html.

[18] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019).