Questions for the Record from Representative Issa for Rachel Goode

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

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1. How do biologics differ from small molecule drugs when it comes to patent-related business practices in the industry?

2. Do new technologies, like AI, improve the efficiency of R&D such that the need to recoup R&D costs using patents is less?

3. What role does PTAB play in your efforts to bring generics and biosimilars to market?

    a. Follow on question: How have recent policy changes at the USPTO affected PTAB and your ability to use it?

    b. Follow on question: Some stakeholders say that PTAB was available for over a decade before the latest changes, but drug prices and patient access have not dramatically improved overall. Are they correct, and how would you respond?

4. Based on your understanding of current U.S. law, can a generic manufacturer produce generics exclusively for export to markets in which either the drug is not under patent or certain uses of that drug are off-patent?

Questions for the Record from Representative Johnson for Dr. Rachel Goode

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

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1. In your opening remarks, you stated that "peer review data shows that about a quarter of pharmaceutical patents are later invalidated and cancelled after being challenged and litigated to a final court decision." Please provide this peer-reviewed data and summarize the methodology used to produce it.

2. In your opening remarks, you cited "real examples of duplicate patents," including a patent claiming treatment of a "human" alongside a patent claiming treatment of a "patient," and a patent claiming treatment of a disease alongside a patent claiming treatment of symptoms of that same disease. Please provide the Subcommittee with patent numbers for both pairs of patents.

3. In your opening remarks, you stated that peer-reviewed research shows the ratio of duplicate patents being litigated by the pharmaceutical industry has increased over time, while the ratio of unique drug patents being litigated has decreased. Please provide that peer-reviewed research along with a brief summary of the methodology used to produce it.

4. In response to a question from Congressman Scott Fitzgerald, you referenced a paper you co-authored with Professor Bernard Chao examining patents litigated in the United States, Canada, and the United Kingdom on the same set of drugs and estimating the time to biosimilar market entry for those drugs. Please provide the Subcommittee with the paper and a summary of its methodology.

    a. Please also identify the source of any data not independently generated by you and Professor Chao, including any estimates of the number of patents covering each drug studied.

    b. In addition, a 2022 study in the *Journal of Law and the Biosciences* by you and Professor Chao stated that "377 patents were asserted against biosimilars in the USA." Please clarify whether this is the same study you referenced in your remarks, and if so, please explain the discrepancy between the "344 patents" figure you used in your remarks and the "377 patents" figure included in the 2022 study.

5. In response to one of my questions, you referenced peer-reviewed data indicating that once patent owners show that a claimed invention is new, useful, and non-obvious over prior art, they do not need to make such a showing for subsequent "duplicate patents." You further stated that "these duplicates add nothing more after the first patent" and that patents with terminal disclaimers are "equivalent to their parent patent."

a. Please provide the peer-reviewed data you referenced in your answer and summarize the methodology used to produce it. In addition, please clarify your statement that terminally disclaimed patents are "equivalent" to their parent patent with regards to novelty, usefulness, and non-obviousness. Finally, please provide a definition for the term "duplicate patent."

6. In response to a question from Congresswoman Laurel Lee, you said the following: "If you look at data going back to 1984, generics are getting on the market quite soon after basic product patent expiry. But if you look at the last 10 years it is a very different picture now that we see these continuation patents and terminal disclaimers increasing." Please provide the relevant peer-reviewed data going back to 1984 and summarize the methodology used to obtain it.

   a. Additionally, please provide peer-reviewed data demonstrating that continuation patents and terminal disclaimers have increased over the last 10 years, accounting for any increase or decrease in the total number of patents filed.

7. In response to a question from Congresswoman Lee, you stated that it takes eight years and costs around $100 million to develop a biosimilar. Please provide the source for these figures and explain the methodology used to calculate them.

8. In response to a question from Congresswoman Lee, you referenced a paper you authored that demonstrates a "huge spike in these duplicate patents issuing out of the Patent Office at year 12." Please provide a copy of this paper and briefly summarize your methodology and identify the source of any data that you did not independently collect or calculate.

   a. In addition, please clarify whether the "duplicate patents" you referred to are patents with terminal disclaimers, and if so, whether and how filing these patents alters the timeline for biosimilar market entry. We are particularly interested in how "put[ting] patents in place at year 12, which is when FDA exclusivity expires on biologics" affects biosimilar manufacturers' ability to launch and compete once FDA exclusivity ends.

9. In response to a question from Ranking Member Jamie Raskin, you stated that "there has been an example of a drug, Myrbetriq, where the first litigation was in 2016, there was subsequent litigation starting with duplicate patents in 2020, and in the end a three year litigation took nine years, because patents can keep issuing even during and after litigation." Please provide data supporting these statements.

10. In response to a question from Congressman Lance Gooden, you pointed to a real-world example of two duplicative patents with only a one-word difference: the word "directly." Please provide identifying information for both patents and provide any additional context regarding this example that you think would be helpful to the Subcommittee.

11. In response to a question from Chairman Darrell Issa, you referenced 2026 data showing that over the last 10 years, the average time it took for biosimilars to reach the market and begin

competing with brand-name biologics was 18 years. Please provide this data to the Subcommittee along with a brief summary of its methodology.

12. In response to a question from Chairman Issa, you stated that the drug Symbravo holds five "unique" patents and 70 "duplicate" patents. Please provide peer-reviewed data supporting these claims and summarize the methodology used.

13. In response to a question from Chairman Issa, you stated that "because the U.S. patent system is so volatile, American patients get access to cheaper drugs later, and less manufacturing can happen in the U.S." Please provide peer-reviewed data to support these claims and explain the methodology behind it. We are particularly interested in data directly supporting the claim that access delays or disparities in domestic manufacturing capacity are caused by volatility in the patent system.

Questions for the Record – Representatives Issa and Johnson for Dr Rachel Goode

Questions for the Record from Representative Issa for Rachel Goode

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

Responses: July 7, 2026

1. How do biologics differ from small molecule drugs when it comes to patent-related business practices in the industry?

Biologics and small molecule drugs share many of the same patent system abusive practices. In both markets, branded drug manufacturers often build patent thickets to inappropriately delay competition by increasing the cost, complexity of patent litigation and business uncertainty for both generic drugs and biosimilars.

Biologics typically present more opportunities to build larger and more complex patent thickets.[1] Because biologics are more structurally complex molecules, branded drug companies have applied strategies currently used to prolong monopolies for small molecule drugs into the biologics arena with great success. One such strategy is the use of ancillary product patents.[2]

This scheme, like patent thickets, is uniquely American, and involves providing inconsistent information to the FDA and the patent office.[3] More specifically, ancillary product patents are being filed on features of a drug

[1] Wouters OJ, Vogel M, Feldman WB, Beall RF, Kesselheim AS, Tu SS. Differential Legal Protections for Biologics vs. Small-Molecule Drugs in the US. JAMA 332(24): 2101-2108 (2024). DOI: 10.1001/jama.2024.16911

[2] Goode R, Feldman WB, Tu SS. Ancillary Product Patents to Extend Biologic Patent Life. JAMA 330(21):2217-2119 (2023).DOI: 10.1001/jama.2023.19547.

[3] Tu SS, Leadmon C, Daval CJR, Kesselheim AS. Inequitable Conduct and Invalidation of FDA-Regulated Product Patents. JAMA 330(21):2119-2121 (2023). DOI: 10.1001/jama.2023.20196.

that were inherently present during the original FDA approval process. Rather than filing ancillary product patents as part of their initial primary patent filing, branded drug companies often keep ancillary product features confidential as trade secrets and wait years before seeking ancillary product patents, prolonging their patent life.[4]

This strategy may allow branded drug companies to extend periods of market exclusivity because later-filed ancillary product patents typically expire after the primary patents. These ancillary product patents cover aspects of the biologic's active ingredient such as glycan profiles, oxidation levels, and other physiochemical properties necessary to obtain FDA approval.

Rather than filing all the existing features of the primary invention as part of the primary patent family, some branded drug companies are filing for patent protection on just the skeleton of the drug's structure. Subsequently, these companies file "ancillary product patents" sometimes a decade later to cover technical features of the drug's structure that were, inherently, present all along and known and used by the FDA to grant regulatory approval. These "trade secrets" being held by the FDA are not available for challengers to use as prior art.[5] This practice extends the period of market exclusivity beyond the initial 20-year patent term and allows "double dipping" as the originator manufacturer can use trade secret protection and patent protection.[6] A fundamental principle of the U.S. patent system dictates that, in exchange for market exclusivity, the invention must be disclosed to the public. This behavior thwarts this basic principle.

However, there is a piece of legislation recently voted out of the Senate HELP Committee that elegantly solves this problem without disrupting innovation incentives. S. 2658, the Medication Affordability and Patent Integrity Act (MAPIA) would curb this behavior by incentivizing patent applicants to fully and accurately disclose the scope of their invention at the time of discovery—particularly when they are already presenting detailed Chemistry, Manufacturing, and Controls (CMC) information to the FDA before clinical trials. The bill discourages the practice of withholding aspects of an invention—such as a biological profile—only to seek additional patents later. If it is established, through discovery, that the later-claimed subject matter was already part of the original invention disclosed to regulators, then those

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[4] Jefferson OA, Nicholson P, Vishnubhakat S, Tu SS, Rai A. The Puzzle of Biologics Manufacturing Platform Patents. Nature Biotechnology 43(3):295-299. (2025) DOI: 10.1038/s41587-025-02579-y.
[5] Robin Feldman, Vaughn Goehrig. Open Secrets. Vanderbilt Journal of Entertainment and Technology Law 2026; 28(4): 709-763.
[6] Goode R, Feldman WB, Tu SS. Ancillary Product Patents to Extend Biologic Patent Life. JAMA. 2023;330(21):2117–2119. doi:10.1001/jama.2023.19547

subsequent patents should not be independently assertable. Patent applicants would certify to the FDA at the time of filing their application to the FDA to request marketing approval that they have been consistent between both the FDA and the USPTO regarding subject matter material to patentability.

Importantly, the underlying invention associated with an original patent itself is not stripped of protection. To the extent the later-claimed subject matter was encompassed in the original invention, it would already have benefited from the original patent—typically a composition-of-matter or product patent—with its full 20-year term. By the time these secondary (follow-on) or ancillary patents are litigated, that original patent has often expired.

The bill does not undermine valid patents or create arbitrary invalidation risk. It targets strategic patenting practices that extend market exclusivity beyond the scope justified by the original invention without providing the public with a commensurate inventive disclosure. Patent holders do not lose legitimate protection—they simply lose the ability to extend it through after-the-fact claims on subject matter they already possessed.

2. Do new technologies, like AI, improve the efficiency of R&D such that the need to recoup R&D costs using patents is less?

Fresenius biopharmaceuticals does not have expertise in this area, as we do not research and development programs for new molecules.

3. What role does PTAB play in your efforts to bring generics and biosimilars to market?

a. Follow on question: How have recent policy changes at the USPTO affected PTAB and your ability to use it?

b. Follow on question: Some stakeholders say that PTAB was available for over a decade before the latest changes, but drug prices and patient access have not dramatically improved overall. Are they correct, and how would you respond?

The claim that IPRs do not help biosimilars or generic drugs access the market is not supported by the evidence. There are clear, real-world examples showing the opposite.

For example, Fresenius Kabi developed and launched a biosimilar to Actemra, a drug used to treat autoimmune diseases and, more recently, COVID-19. They filed inter partes review (IPR) challenges against five patents covering this product, and all were successfully instituted.[7] As a result, Fresenius Kabi was able to launch our biosimilar in April 2024, eight years before the expiry of the

[7] PTAB Tracker | Big Molecule Watch

last asserted patent. At the time of launch, court litigation had only just begun, so it was the IPR process that enabled this significantly earlier patient access, well before traditional litigation would have been resolved.

This is not an isolated example. Empirical research has shown that the IPR pathway was used for a number of biologics.[8] For those biologic IPR decisions that went to final written decision, most had claims invalidated. Most of these invalidated patents were secondary patents. Importantly, successful IPR challenges enabled biosimilar market entry, after which brand-product revenues declined, consistent with increased competition leading to lower prices.[9]

Additionally, empirical research by Professor Charles Duan identifies multiple case studies in which generic drugs entered the market rapidly after successfully challenging invalid patents through IPRs, rather than waiting for protracted court proceedings to progress. His paper shows that in each case, generic entry led to substantial reductions in drug prices, demonstrating the direct link between IPRs, market entry, and affordability.[10]

These outcomes reflect the structural advantages of IPRs. They provide a faster and more expert forum for assessing patent validity, with technical judges and the ability to test evidence through expert submissions and cross-examination. This makes them a particularly effective tool for clearing weak or invalid patents that would otherwise delay competition.

However, despite their importance, IPRs are becoming increasingly inaccessible. Institution rates have dropped sharply, from around 61% between January and August 2024 to approximately 28% between October 2024 and August 2025. Concerningly, the number of petitions filed per month has declined significantly over the same period. These trends are largely driven by sweeping discretionary denials based on policies that were implemented without formal rulemaking.

There is also a troubling increase in denials on the merits that are issued without any substantive explanation. In these cases, the only indication of the decision is that the patent appears on a list of IPRs denied "on the merits,"

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[8] Van de Wiele V, Kesselheim AS, Tu SS. Biologic Patent Challenges Under the AIA. Nature Biotech 42(3):374-377 (2024). DOI: 10.1038/s41587-024-02156-9.

[9] Raymakers A, Van de Wiele V, Kesselheim AS, Tu SS. Changes in Biologic Drug Revenues After Administrative Patent Challenges. Health Affairs 44(3): 274-279 (2025). DOI: 10.1377/hlthaff.2024.00504.

[10] American University. Law Review. 72 Am. U. L. Rev. 1177 (2023). On the Appeal of Drug Patent Challenges, Author: Charles Duan

with no reasoning provided. In practice, these decisions closely resemble discretionary denials, raising concerns that this classification may be used to make discretionary denial statistics appear more favorable.

The practical impact is significant. Generic and biosimilar companies are now being advised by counsel to avoid filing IPRs altogether. This is because even a denial, regardless of the underlying reasoning, can be used by branded drug companies to suggest that a patent is strong on its merits, potentially influencing how courts perceive the patent in litigation.

As a result, one of the most effective and fast mechanisms for enabling timely biosimilar and generic entry is being undermined. If the goal is to improve patient access to lower-cost medicines, the availability of IPRs must be restored in line with the statute.

4. Based on your understanding of current U.S. law, can a generic manufacturer produce generics exclusively for export to markets in which either the drug is not under patent or certain uses of that drug are off-patent?

No, generic/biosimilar companies cannot "make, use, import or sell" their drugs in the U.S. until the relevant patents are invalidated or shown not to be infringed.[11] Because of patent thickets and ancillary product patents, and because this gamesmanship is not rife abroad, the U.S. is typically the last country where a biosimilar can be manufactured.[12] This means that generic/biosimilar manufacturers cannot launch their drugs in other countries as net exporters from the U.S. Even if a manufacturer does not sell a single dose of a biosimilar in the U.S. and solely exports to the E.U., they would infringe relevant U.S. patents by making the biosimilar in the U.S.[2] The delayed launches of complex generics and biosimilars compared to the EU is due to abuse of the U.S. patent system that keep U.S. patients paying more for longer than in the E.U. This undermines the ability of drug manufacturers to produce medicines in the United States and create high-paying domestic jobs. In addition, enabling manufacturers to establish production facilities in the U.S. could help reduce drug shortages, as those companies would have the flexibility to shift capacity and manufacture other needed medicines domestically.

[11] https://www.law.cornell.edu/uscode/text/35/271?utm_source=chatgpt.com

[12] Goode R, Chao B. Biological patent thickets and delayed access to biosimilars, an American problem. J Law Biosci. 2022 Sep 1;9(2):lsac022. doi: 10.1093/jlb/lsac022. PMID: 36072417; PMCID: PMC9439849.

Questions for the Record from Representative Johnson for Dr. Rachel Goode

"Medicines and IP: Balancing Innovation and Access"

June 4, 2026

Thank you, Representative Johnson, for these thoughtful questions. Because many of these questions are directly related to peer-reviewed data, I'd like to spend some time comparing the peer-reviewed data that we rely on as compared to data that was referred to in the hearing and in letters sent to Congress to rebut our assertions about patent thickets.

Peer-review exists to foster full transparency, full disclosure, and full accountability. While there are numerous peer-reviewed papers documenting the existence of patent thickets, many individuals and groups continue to ignore them and instead fixate on finding flaws in I-MAK data that has no relevance to the evidence supporting the ETHIC Act.

My analysis is based on patents actually asserted against biosimilars—not merely the number of patents filed. If a branded drug company believes its inventions are patentably distinct, it should argue that before the patent examiner and avoid filing a terminal disclaimer. There is no economic reason that a patent holder would ever disclaim part of a patent term if they weren't forced to after an obviousness-type double patenting rejection. Opponents of the ETHIC Act have not produced peer-reviewed evidence that the patent thicket strategies do not exist. Instead, they rely on vague analogies about other products that are heavily patented, China, terminal disclaimers as a tool for the patent office to organize claims and defending innovation.

But "protecting innovation" doesn't apply here. In fact, the ETHIC Act is a pro-innovation bill. American innovation should not be judged on the quantity of its patents but on the quality of its patents. The ETHIC Act "clears out the clutter" and incentivizes brand drug companies to innovate more uses for old drugs rather than stacking duplicate patents on their old cash cows.

Filing a terminal disclaimer is effectively an admission that the new patent is not patentably distinct from earlier patents owned by the same entity. If a patent truly reflected a genuine innovative improvement, the owner would decline the disclaimer and pursue the full term. They do not, because these patents could not be granted without it. In short, these patents add no value to American innovation.

While critics attempt to cast doubt on whether peer-reviewed data establishes the existence of patent thickets, we have seen a steady stream of opposition to the ETHIC Act from organizations whose own motivations are

far from transparent. Take the Trade Alliance to Promote Prosperity: its stated mission is to protect innovation in international trade agreements, yet it has suddenly taken strong positions on the 340B program, a hallmark issue for branded pharmaceutical companies.13 This raises the obvious question of whether those drug companies are operating behind the scenes through such trade groups to advance their interests.

Then there's We Work for Health, which has the appearance of a PhRMA (branded drug trade association)-backed effort. They, too, have come out against this bill. And C4IP, staffed by a former employee of yours, continues to work to block even the most reasonable patent abuse reforms, effectively helping to keep drug prices high. It is fair to ask: who is funding C4IP, a 501(c)(4) advocacy organization, and why were they called to testify, along with a law firm representing the branded industry? Was there not a single branded company witness willing to testify in public on this legislation that they contend so fervently would destroy U.S. innovation? If they are doing nothing to abuse the U.S. patent system, why not send a company representative responsible for patent prosecution?

Throughout the hearing, I relied on empirical data and concrete examples, while other witnesses on the panel made vague assertions such as "it's not that simple," or "we need to avoid driving R&D to China." But where is the evidence supporting those claims?

Finally, pointing to a USPTO "study" that selectively highlights a small number of drugs to construct a patent maximalist narrative is not a sound basis for policy.[14] The USPTO report exemplifies how patent owner narratives can be advanced by relying on the wrong data to reach flawed conclusions. It examines just 13 drugs, 70% of which (9 out of 13) were litigated before 2010, well before patent thickets became an entrenched strategy. Peer-reviewed data shows the patent system functioned relatively well in the initial decades of Hatch Waxman (see my answer to Q6, below), so analyzing older cases offers little insight into current trends. The report even includes aspirin, excludes biologic drugs that typically involve far more patents than

13 New TAPP Cartoon Illustrates: 340B Drug Program Is Painfully Out of Control — Trade Alliance to Promote Prosperity

[14] USPTO's Drug Patent and Exclusivity Study, produced in collaboration with the FDA at the request of Senator Thom Tillis (R-NC) https://www.uspto.gov/sites/default/files/documents/USPTO_Drug_Patent_and_Exclusivity_Study_Report.pdf

small-molecule generics,[15] and includes Imbruvica while missing a substantial portion of its patent filings because the study period ended before many of them were submitted.[16] In short, this is a classic example of cherry-picked data, and it would not withstand meaningful peer-review scrutiny. As of 2024, there were 41 patents listed in the orange book covering Imbruvica, and 31 of those patents were subject to a terminal disclaimer. This means that 75% of the listed patents are non-innovative duplicates.

The claim by other witnesses, based on this USPTO report, that the number of patents litigated against generics and biosimilars "remained stable" from 2018 to 2022 is misleading. The report itself cautions against drawing such broad conclusions from its limited data set. It explicitly states on page four that "This study does not contain sufficient data for generalized findings concerning all Orange Book listed patents and the timing of marketing of all generic drugs," and on page 57 that "The sample size limits generalizations that can be drawn from the study, and the conclusions that follow focus on observations about the studied products."

Taken together, these methodological flaws mean the USPTO report does not provide a reliable picture of current pharmaceutical patenting practices and would be unlikely to withstand rigorous peer-review scrutiny. Congress should instead rely on comprehensive, peer-reviewed evidence when assessing the impact of patent thickets on competition, drug prices, and patient access.

1. In your opening remarks, you stated that "peer reviewed data shows that about a quarter of pharmaceutical patents are later invalidated and cancelled after being challenged and litigated to a final court decision." Please provide this peer-reviewed data and summarize the methodology used to produce it.

S. Sean Tu & Mark A. Lemley, What Litigators Can Teach the Patent Office About Pharmaceutical Patents, 99 WASH. L. REV. 1673, 1682, 1709 (2022).

- See Abstract "*We find that about 25% of active Orange Book patents [litigated to final judgment] were invalidated in court*.".
- See page 1700 "*We note that most of the patents that undergo litigation are not "original" patents. As shown in Table 1, only 21% of invalidated patents are original, while 73% of invalidated are continuation applications*"

[15] Wouters OJ, Vogel M, Feldman WB, Beall RF, Kesselheim AS, Tu SS. Differential Legal Protections for Biologics vs. Small-Molecule Drugs in the US. JAMA 332(24): 2101-2108 (2024). DOI: 10.1001/jama.2024.16911. [The average number of biologic patents is 14 vs 3 for small molecules].
[16] Larvol Delta

2. In your opening remarks, you cited "real examples of duplicate patents," including a patent claiming treatment of a "human" alongside a patent claiming treatment of a "patient," and a patent claiming treatment of a disease alongside a patent claiming treatment of symptoms of that same disease. Please provide the Subcommittee with patent numbers for both pairs of patents.

US8889135 Claim 1	US9073987 Claim 1
1. A method for treating rheumatoid arthritis in a human subject, comprising administering subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13 - 15 days for a time period sufficient to treat the rheumatoid arthritis, wherein the anti-TNFα antibody [is adalimumab]	1. A method of reducing signs and symptoms in a patient with moderately to severely active rheumatoid arthritis, comprising: administering to said patient a total body dose of 40 mg of a human anti-TNFα antibody, wherein the dose is administered subcutaneously from a 40 mg dosage unit form once every 13-15 days, and wherein the anti-TNFα antibody [is adalimumab]

This is not an isolated incident. Here is an example from the patent thicket: Restasis. FDA approved Cycloisporine (injectable) NDA 050573 in 11/14/1983. These terminally disclaimed continuation patents to a secondary invention were transferred to the St. Regis Mohawk tribe to avoid invalidation (sovereign immunity) in 2017.[17] Please note that keratoconjunctivitis sicca is the formal term (ICD10) for dry eye disease.[18]

Asserted Patent No.	**Terminal Disclaimer**	**Assigned to St. Regis Mohawk Tribe**	**Claims Variations**
8629111	Yes (TD to three applications)	Yes	Formulation of RESTASIS used for treating an eye
8648048	Yes (TD to one application)	Yes	Method of increasing tear production using RESTASIS
8685930	Yes (TD to seven applications)	Yes	Formulation of RESTASIS used for treating an eye having keratoconjunctivitis sicca

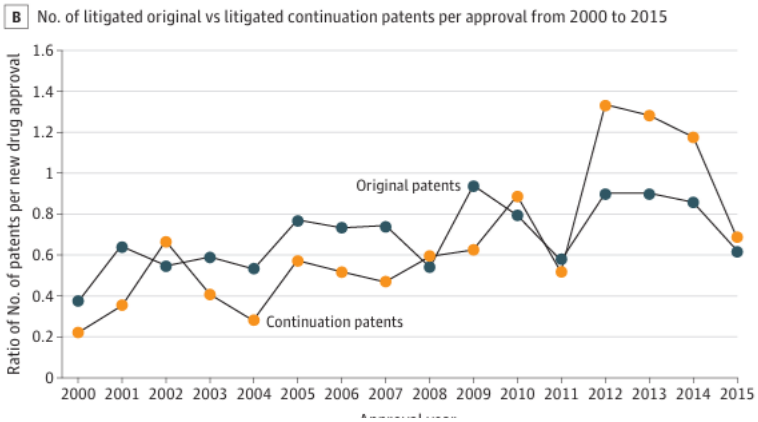
[17] The Restasis Patents and Tribal Sovereign Immunity: New Developme
[18] Understanding Keratoconjunctivitis Sicca (Dry Eye) - ICD-10 Code H16.229

9248191	Yes (TD to five patents, including each of the patents above)	Yes	Method of treating dry eye disease using RESTASIS

3. In your opening remarks, you stated that peer-reviewed research shows the ratio of duplicate patents being litigated by the pharmaceutical industry has increased over time, while the ratio of unique drug patents being litigated has decreased. Please provide that peer-reviewed research along with a brief summary of the methodology used to produce it.

Tu SS, Kesselheim AS, Wetherbee K, Feldman WB. Changes in the Number of Continuation Patents on Drugs Approved by the FDA. JAMA. 2023 Aug 1;330(5):469-470. doi: 10.1001/jama.2023.11525. PMID: 37526728; PMCID: PMC10394575.

- The authors extracted patents listed on drugs in the Orange Book from January 1, 2000, to December 31, 2021, and categorized each patent as original or continuation using the Google Patents Public Data Sets on Google BigQuery. See Methodology section for more details.
- See results, page 470: Over 15 years the proportion of continuation patents in litigation increased by 213%.
- See Table B, which shows that in earlier years the ratio of original patents to continuation patents is higher, whereas in later years the ratio shifts, with continuation patents exceeding original patents.



Carrier, M. A., & Tu, S. S. (2024). *Why pharmaceutical patent thickets are unique* (SSRN Scholarly Paper No. 4571486). SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4571486

- See page 91; *"This 265% increase in Purple Book patents was accompanied by a significant increase in Purple Book continuations (which, again, by definition were litigated given such a requirement for listing). From 2003 to 2013, 7 of the 20 Purple Book patents (35%)*

were continuations, but from 2014 to 2020, that figure rose more than 180% to 45 of 46 (98%)"

4. In response to a question from Congressman Scott Fitzgerald, you referenced a paper you co authored with Professor Bernard Chao examining patents litigated in the United States, Canada, and the United Kingdom on the same set of drugs and estimating the time to biosimilar market entry for those drugs. Please provide the Subcommittee with the paper and a summary of its methodology.

Rachel Goode, Bernard Chao, Biological patent thickets and delayed access to biosimilars, an American problem, *Journal of Law and the Biosciences*, Volume 9, Issue 2, July-December 2022, lsac022, https://doi.org/10.1093/jlb/lsac022

Summary of Methodology

The study examined whether the number of patents asserted against biosimilar manufacturers is associated with delays in biosimilar market entry by comparing patent litigation involving the same biologic medicines across the United States, Canada, and the United Kingdom.

Specifically, the methodology involved:

- **Selection of comparable products.** The analysis was limited to all biosimilars that had sought regulatory approval in all three jurisdictions. Restricting the dataset to the same biosimilar products minimized differences attributable to the characteristics of individual drugs or manufacturers and allowed for a like-for-like international comparison.
- **Collection of patent litigation data.** For each biosimilar, the authors identified the patents asserted by reference product sponsors during patent litigation or related patent proceedings in each country. The study measured the number of patents actually asserted, rather than simply counting patents listed in patent registers, because asserted patents represent those relied upon to delay or prevent market entry.
- **Measurement of market-entry timing.** For each biosimilar, the study compared the time between regulatory approval and commercial market entry in the United States, Canada, and the United Kingdom. This allowed the authors to examine whether jurisdictions with larger numbers of asserted patents also experienced longer delays before patients gained access to biosimilars.

- **Cross-country comparison.** The study then compared both (1) the number of patents asserted and (2) the length of time to biosimilar market entry across the three jurisdictions. The analysis found that, on average, nine to twelve times more patents were asserted against biosimilars in the United States than in Canada or the United Kingdom. The study found that biosimilars generally entered the Canadian and UK markets an average of 7 and 4 months, respectively, and after an average of 34 months in the United states following regulator approval.

a. Please also identify the source of any data not independently generated by you and Professor Chao, including any estimates of the number of patents covering each drug studied.

The number of patents was not estimated. Rather, the study counted the actual patents asserted by the branded drug company in the initial complaint that commenced the litigation. As a result, only the patents that the branded drug company itself chose to enforce against the biosimilar manufacturer were included in the analysis. In other words, the study relied on the branded drug companies' own litigation filings, rather than estimates or independent assumptions. This likely understates the size of the biologic patent thicket because not every patent is litigated. In addition, many companies strategically reserve patents, asserting different patents against different defendants in separate litigations.

In order to assess the number of patents asserted against each of the 30 biosimilars in the UK litigation documents were downloaded from the following commercially available databases: CE-File (Court filing system) [https://efile.cefile-app.com], Westlaw [https://uk.westlaw.com], Darts-IP [https://app.darts-ip.com], and EMA [https:// www.ema.europa.eu/en]. Litigation documents in the USA were downloaded from PACER [https://pacer.u scourts.gov/]. For each of the 30 biosimilars, the biosimilar manufacturer name and the name of the respective branded pharmaceutical company were searched in the patent litigation databases. Publicly available litigation documents were downloaded and reviewed in order to determine which patents were litigated in each country. In Canada, there is no online portal for Federal Court files; therefore, we contacted the court registry directly and obtained litigation documents by email.

b. In addition, a 2022 study in the Journal of Law and the Biosciences by you and Professor Chao stated that "377 patents were asserted against biosimilars in the USA." Please clarify whether this is the same study you referenced in your remarks, and if so,

please explain the discrepancy between the "344 patents" figure you used in your remarks and the "377 patents" figure included in the 2022 study.

The correct figure from the study is 377 litigated patents in the United States, and I appreciate the opportunity to clarify the record. See page 23 of the paper. This is in comparison to 50 in the UK and 20 patents in Canada against the same biosimilars.

5. In response to one of my questions, you referenced peer-reviewed data indicating that once patent owners show that a claimed invention is new, useful, and non-obvious over prior art, they do not need to make such a showing for subsequent "duplicate patents." You further stated that "these duplicates add nothing more after the first patent" and that patents with terminal disclaimers are "equivalent to their parent patent." a. Please provide the peer-reviewed data you referenced in your answer and summarize the methodology used to produce it. In addition, please clarify your statement that terminally disclaimed patents are "equivalent" to their parent patent with regards to novelty, usefulness, and non-obviousness. Finally, please provide a definition for the term "duplicate patent."

The term "duplicate patent" refers to terminally disclaimed continuation patents. Continuation patents are prohibited from adding "new matter" and typically share the same specification as a previously filed patent. Most continuation patents require a terminal disclaimer because the patent examiner finds that they are too similar to an earlier patent and should not receive additional years of patent protection. When an applicant files a terminal disclaimer they admit that the patent in question is "not patentably distinct" to a previously filed patent.

Some have contended that the ETHIC Act would encourage innovators to avoid filing terminal disclaimers and instead seek patents with later expiration dates. This claim misunderstands how patent law operates. Absent a terminal disclaimer, duplicative patents would not grant, as they would violate well-established double-patenting rules. In practice, terminal disclaimers are filed in response to, or in anticipation of, patent office rejections where claims are not meaningfully distinct from an existing patent.

Importantly, the foundational patent in a terminally disclaimed family—the parent patent—is the patent that reflects a bona fide incremental innovation, having met the statutory requirements of novelty and non-obviousness over prior art. Subsequent patents in the family do not extend that innovation; they merely replicate it, sharing the same priority filing and expiration date.[19] Because they are examined against the same prior art date, any truly novel

[19] Chao B, Whalen R, Kesselheim AS, Tu SS. Clearing Dense Drug-Patent Thickets. New England Journal of Medicine 391(23):2180-2182 (2024). DOI: 10.1056/NEJMp2412999.

and non-obvious claims would qualify for an independent 20-year term. The absence of such claims demonstrates that these patents are substantively duplicative, with only minor linguistic variations rather than meaningful scientific distinctions. In other words, they are practically ”equivalent” to the patent to which they are tied by a terminal disclaimer.

In MPEP § 201.07 (implementing 37 CFR 1.78) that makes clear a continuation application must not add new matter:

- "A continuation application is an application for the invention(s) disclosed in a prior-filed copending … application. **The disclosure presented in the continuation must not include any subject matter which would constitute new matter if submitted as an amendment to the parent application.**" [bitlaw.com]
- Obviousness-type double patenting prevents an applicant from obtaining a second patent with claims that, based on their claim language, are not patentably distinct because they are merely an obvious variation of claims in an earlier patent. Under 37 CFR § 1.321(c), applicants must file a terminal disclaimer to obviate such rejections.

The ETHIC Act does not undermine innovation—it curbs gamesmanship. By removing incentives to accumulate redundant patents that offer no new therapeutic benefit, the Act reinforces the principle that patent protection should correspond to genuine scientific advancement. In doing so, it strengthens the integrity of the patent system and better aligns it with patient and public interest.

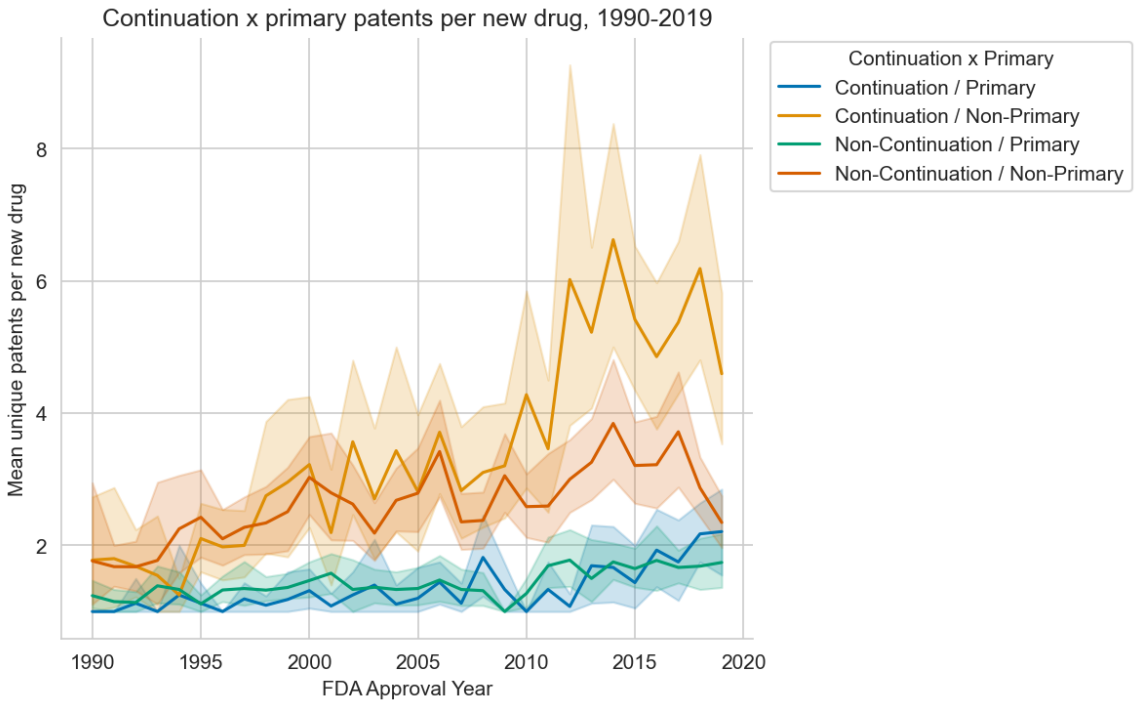
6. In response to a question from Congresswoman Laurel Lee, you said the following: "If you look at data going back to 1984, generics are getting on the market quite soon after basic product patent expiry. But if you look at the last 10 years it is a very different picture now that we see these continuation patents and terminal disclaimers increasing." Please provide the relevant peer-reviewed data going back to 1984 and summarize the methodology used to obtain it.

a. Additionally, please provide peer-reviewed data demonstrating that continuation patents and terminal disclaimers have increased over the last 10 years, accounting for any increase or decrease in the total number of patents filed.

A landmark, exhaustive study conducted by Professor Sean Tu of the University of Alabama School of Law, which took two years to complete, analyzed data from over 10,000 patents listed in the FDA's Orange Book on drugs obtaining FDA approval from 1990 to 2019. The study analyzed all small-molecule drugs approved by the FDA between 1990 and 2019 and examined every associated Orange Book patent, using patent records to

identify filing dates, expiration dates, and whether patents were original or continuation patents. The researchers manually classified patents as either primary (covering the active ingredient itself) or non-primary (covering later innovations such as formulations, methods of use, or delivery devices) and further categorized non-primary patents by type (formulation, method of use, device, etc.). They then evaluated how these patents affected the duration of patent protection and identified which patents had been asserted against generic manufacturers in litigation to assess the role of later-filed patents in extending exclusivity and delaying generic entry.

The paper has successfully completed peer review and is currently "in press," meaning it is scheduled for publication after revisions. With special permission from both the *Journal of the American Medical Association (JAMA)* and the study's authors, I have been authorized to share the figures and methodology from the paper with you here.



This figure shows that the use of continuation patents for primary patents has remained relatively stable over time (green line). By contrast, there has been a significant increase in the use of continuation patents for non-primary patents (amber line). These non-primary patents typically expire later than the primary patents and are often more vulnerable to invalidity challenges. In other words, the data suggests that branded drug companies are increasingly concentrating their duplicate patenting strategy on later-filed,

weaker patents in order to extend the overall patent estate beyond the expiration of the core patents covering the drug itself.

The timeline at the bottom shows the FDA approval date for the branded drug. For branded drugs, listing of patents in the Orange Book tends to peak around nine years after FDA approval.[20] The timing is deliberate to increase risk for generic entrants.[21] As a result, drugs that have been on the market for nine years or less have generally not yet received most of their continuation patents.

This timing effect explains why the graph shows fewer continuation patents for the newest drugs. Because these products are still relatively young, many of their continuation patents have not yet been issued and therefore are not yet reflected in the data. Consequently, the decline seen in the most recent years should not be interpreted as a true reduction in continuation patenting activity. Rather, it reflects the fact that the patent estates of newer drugs are still developing and have yet to blossom into the dense patent thickets that pose the greatest challenges for generic entrants. If the analysis were extended into the future and these drugs were allowed to mature, the expectation is that the upward trend in continuation patents would continue, consistent with the pattern observed throughout most of the graph before the apparent dip in the final years.

Turning to the next graph from this seminal paper, the data show that the gap between the first-expiring patent and the last-expiring patent listed in the Orange Book for each branded drug has grown steadily over time. In other words, the period of patent protection surrounding a drug is becoming increasingly stretched out, see below:

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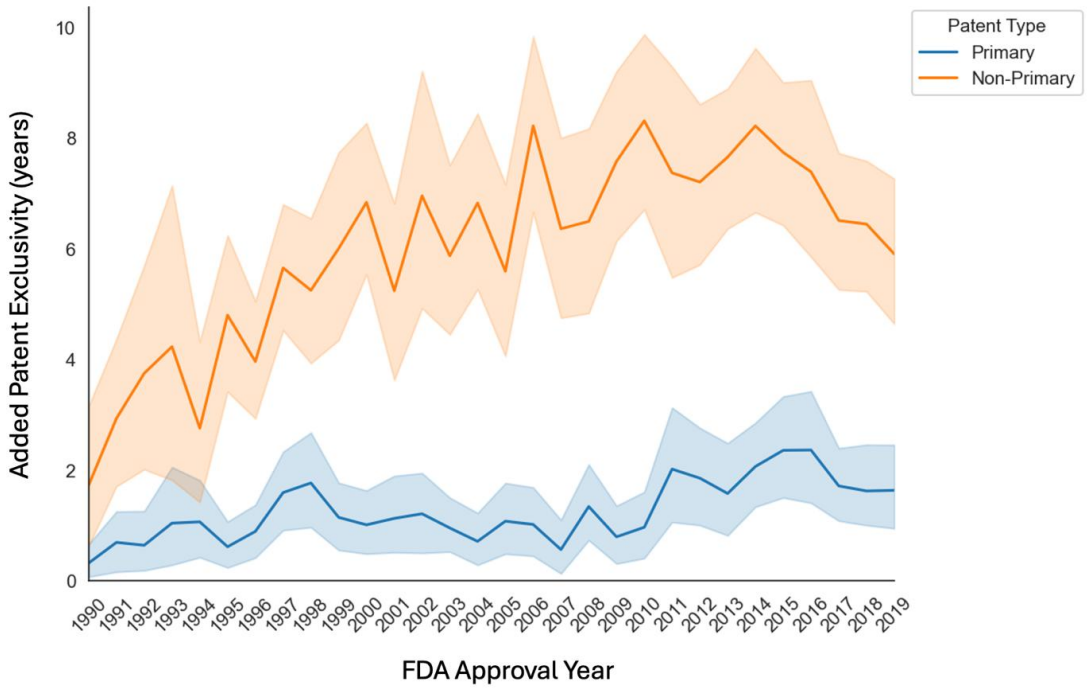
[20] Tu SS, Kesselheim AS, Ross JS, Gupta R. Revenue, Patents, and New Generic Competition for Prescription Drugs in the USA. J Gen Intern Med. 2026 Jan;41(1):245-248. doi: 10.1007/s11606-025-09717-x. Epub 2025 Jul 14. PMID: 40659975; PMCID: PMC12855703.

[21] Tu SS, Feldman WB. Use of Track One Prioritized Examination for Pharmaceutical Patents. JAMA Health Forum 5(7):e241886 (2024). DOI: 10.1001/jamahealthforum.2024.1886.



This finding suggests that patent thickets are not only growing in size, through the accumulation of additional patents, but also in duration. As we move from older drugs on the left side of the graph to newer drugs on the right, later-filed secondary patents are extending patent expiry dates further beyond the expiration of the original patents covering the drug. In 1990 non-primary patents added only 1-2 years of patent exclusivity. By contrast, newer drugs now experience 7-8 years of additional patent life.

The effect of these large thickets is to increase uncertainty about when generic entry can occur, thereby adding risk, transaction costs ultimately leading to delayed generic entry. As discussed in our response to Question 8a below, this uncertainty can delay generic manufacturers' ability to plan market entry and increases the legal risks associated with challenging patents. Over time, this can contribute to delayed patient access to lower-cost generic medicines.

7. In response to a question from Congresswoman Lee, you stated that it takes eight years and costs around $100 million to develop a biosimilar. Please provide the source for these figures and explain the methodology used to calculate them.

These figures are based on my industry experience and expertise. For additional context, see the external references here, which are broadly consistent with this range: https://biosimilarscouncil.org/resource/streamlining-the-development-of-biosimilar-medicines/

8. In response to a question from Congresswoman Lee, you referenced a paper you authored that demonstrates a "huge spike in these duplicate patents issuing out of the Patent Office at year 12." Please provide a copy of this paper and briefly summarize your methodology and identify the source of any data that you did not independently collect or calculate.

Tu SS, Goode R, Feldman WB. Biologic Patent Thickets and Terminal Disclaimers. *JAMA.* 2024;331(4):355–357. doi:10.1001/jama.2023.25389

The study examined the use and timing of terminal disclaimers among biologic patents involved in U.S. biosimilar litigation and found a substantial increase in the issuance of terminally disclaimed patents at 12 years after the branded drug obtained FDA approval, coinciding with the end of FDA-granted statutory biologic exclusivity. This is the time point I referenced during the hearing. The paper concludes by adding patents with terminal disclaimers beginning in year 12, branded drug companies introduce uncertainty precisely when biosimilar challenges begin. Biosimilar firms must then contest or design around a wave of new patents containing claims that become enforceable just as statutory exclusivity periods are ending.[22]

Methodology

The study identified every biologic patent asserted in U.S. biosimilar litigation between 2010 (when the biosimilars litigation pathway was first established) and 2023 (when the data was collected). For each litigated patent, we determined whether it had been subject to a terminal disclaimer and analyzed the timing of patent issuance. This allowed us to examine when terminally disclaimed patents were issuing over the life of a biologic drug and to compare those patterns with patents that were not subject to terminal disclaimers.

Data Sources

The patent data were obtained from publicly available U.S. Patent and Trademark Office (USPTO) patent records, including patent documents and terminal disclaimer filings. Information identifying patents asserted in biosimilar litigation was compiled from publicly available federal court records and LexMachina.

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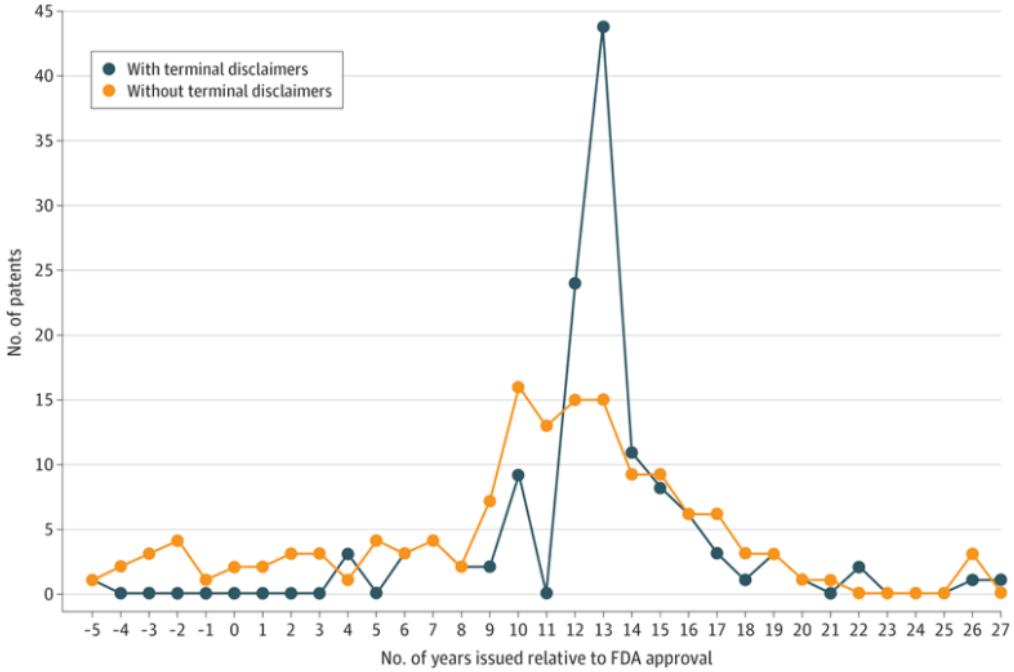
[22] Tu SS, Feldman WB. Use of Track One Prioritized Examination for Pharmaceutical Patents. JAMA Health Forum 5(7):e241886 (2024). DOI: 10.1001/jamahealthforum.2024.1886. [There is a spike in track one patents in year 12 for biologic drugs]

a. In addition, please clarify whether the "duplicate patents" you referred to are patents with terminal disclaimers, and if so, whether and how filing these patents alters the timeline for biosimilar market entry. We are particularly interested in how "put[ting] patents in place at year 12, which is when FDA exclusivity expires on biologics" affects biosimilar manufacturers' ability to launch and compete once FDA exclusivity ends.

Yes, the paper studies patents having terminal disclaimers. This is what I meant by "duplicate patents". Please see the graphic below detailing the timing and volume of terminally disclaimed continuation patents (duplicates) vs. patents distinct from each other:[23]

Figure. Number of Patents With vs Without Terminal Disclaimers Involved in Litigation Relative to Drug Approval From the US Food and Drug Administration (FDA)



Go to Figure in Article

This figure shows when litigated patents with vs without terminal disclaimers were granted relative to the approval of biologics by the FDA. Both types of patents experienced sharp increases during the study period followed by declines through year 20. The pronounced peak for patents with terminal disclaimers occurred in years 12 and 13, coinciding with the end of FDA-granted statutory exclusivity.

The principal impact of patents issuing around year 12 is the business uncertainty they create for biosimilar manufacturers during development and launch planning.

Developing a biosimilar typically takes approximately eight years. As a result, a biosimilar developer must make substantial investments and development

[23] Tu SS, Goode R, Feldman WB. Biologic Patent Thickets and Terminal Disclaimers. *JAMA.* 2024;331(4):355–357. doi:10.1001/jama.2023.25389

decisions years before the anticipated expiration of the reference product's FDA exclusivity. At the outset of development, there may be only a relatively small number of patents associated with the biologic. However, as demonstrated in the referenced paper, the number of patents increases dramatically over time, with a substantial spike in duplicate patents issuing around year 12, when FDA exclusivity expires and biosimilar competition first becomes possible.

This changing patent landscape creates significant uncertainty because the biosimilar manufacturer cannot reliably predict the scope of the patent estate it will ultimately face at launch. By the time the biosimilar is ready for market, the number of asserted patents may have increased many-fold.

The resulting volume of patents presents practical challenges for the legal system, which harms business certainty. Federal courts are not structured to litigate scores of patents simultaneously. Patent litigation typically takes years, and courts generally narrow the number of patents that proceed to trial only after extensive discovery and litigation. There is no legal requirement that a branded manufacturer limit the number of patents it asserts.

Proceedings before the Patent Trial and Appeal Board (PTAB), where available, could provide an efficient mechanism for challenging weak patents. However, PTAB proceedings become economically impractical when a biosimilar manufacturer is faced with dozens of patents. Consequently, if a branded company obtains multiple substantially duplicative patents covering the same invention, the sheer number of patents may effectively shield weaker patents from PTAB review because it is prohibitively expensive to challenge every duplicate patent individually via the PTAB.

The financial imbalance is stark: patents cost about $25,000 to prosecute and issue but challenging them via the PTAB costs roughly $1 million per IPR and far more in district court.[24] This economic asymmetry (not innovation) drives delayed generic and biosimilar entry. Terminal disclaimer practices allow endless attempts to defend the same invention, turning invalid patents into years of extra monopoly profits while litigation drags on.[25]

The issuance of additional patents during the later stages of product development also creates the risk of serial litigation. A biosimilar

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[24] *2023 American Intellectual Property Law Association 2023 Report of the Economic Survey*. Arlington, VA: American Intellectual Property Law Association; 2023 https://fundamentalpatlit.com/wp-content/uploads/2024/02/AIPLA.pdf

[25] Bonis T, Kesselheim AS, Tu SS. Serial Patent Litigation: An Emerging Strategy to Delay Entry of Generic Competition. Health Affair Scholar 2025; 3(11): qxaf240. DOI: 10.1093/haschl/qxaf240.

manufacturer may successfully resolve litigation over an existing patent portfolio, only to have a newly issued patent emerge shortly before launch with claims containing different descriptive terms that require an entirely new litigation. This continuing uncertainty can delay market entry, increase litigation costs, and complicate commercial planning even after years of investment in biosimilar development.

9. In response to a question from Ranking Member Jamie Raskin, you stated that "there has been an example of a drug, Myrbetriq, where the first litigation was in 2016, there was subsequent litigation starting with duplicate patents in 2020, and in the end a three year litigation took nine years, because patents can keep issuing even during and after litigation." Please provide data supporting these statements.

The data supporting this statement are set out in the peer-reviewed article, *Serial patent litigation: an emerging strategy to delay entry of generic competition*, published in *Health Affairs Scholar*.[26] The article discusses Astellas's overactive bladder drug mirabegron, sold as Myrbetriq, as an example of serial patent litigation.

Myrbetriq is a chronic medication used to treat overactive bladder. The article reports that it has an estimated average annual net price of approximately $977.

The first Hatch-Waxman patent infringement lawsuit involving prospective generic versions of Myrbetriq began in October 2016. However, after that initial litigation, the article identifies five rounds of litigation involving Myrbetriq, lasting approximately nine years and two months. The article's table identifies the potential generic delay as five years and ten months.

The article also provides patent claim-level evidence showing the repetitive nature of the later litigations. Box 1 compares claims from the patents asserted in the second through fifth Myrbetriq lawsuits. The article explains that the patents asserted in the fourth and fifth litigations were continuation patents, that had "no substantial differences" from the patents asserted in the second and third litigations, see Box 1, below.

[26] Timothy Bonis, Aaron S Kesselheim, Sean Tu, Serial patent litigation: an emerging strategy to delay entry of generic competition, *Health Affairs Scholar*, Volume 3, Issue 12, December 2025, qxaf240, https://doi.org/10.1093/haschl/qxaf240

Box 1. Mirabegron litigated patent claims.

Litigation 2 (2017)	Litigation 4 (2024)
Original Patent (10 842 780)	Continuation Patent (12,059,409)
"A pharmaceutical composition, comprising [mirabegron]…in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of 100,000 to 8,000,000…"	"A tablet, comprising [mirabegron]…in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of 200,000 to 7,000,000…"
"…wherein the hydrogel-forming polymer is at least one compound selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer."	"…wherein the hydrogel-forming polymer is polyethylene oxide."
"…wherein the additive is at least one selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, D-mannitol, D-sorbitol, xylitol, lactose, sucrose…" (20 additives listed)	"…wherein the additive is polyethylene glycol"

Litigation 3 (2020)	Litigation 5 (2024)
Original Patent (11,707,451)	Continuation Patent (12,097,189)
"A method for treating overactive bladder… the method comprising administering orally to a subject in need thereof a tablet comprising 10 mg to 200 mg of [mirabegron] in a sustained release formulation…selected from the group consisting of a sustained release hydrogel-forming formulation, a multi-layered formulation [], a gel formulation [], an osmotic pump type formulation [], a matrix formulation [], a modified release formulation [], and a matrix formulation []."	"A method for treating overactive bladder…the method comprising administering orally to a subject in need thereof a tablet comprising **25** mg of [mirabegron] in a sustained release hydrogel-forming formulation"
"wherein the reduced food effect is compared to that after oral administration of an immediate release formulation comprising [mirabegron]."	"wherein the reduced food effect is compared to that after oral administration of an immediate release formulation comprising [mirabegron] and is a difference…of C_{max} of 10% or more…"

Examples of claims from the patents asserted in mirabegron lawsuits 2 to 5. The patents in litigations 4 and 5 have no substantial differences from the patents in litigations 2 and 3.

The article concludes that this serial litigation strategy impeded broader generic entry regardless of whether Astellas ultimately prevailed on the merits. According to the article, the litigation compelled other generic competitors to delay or abandon market entry, thereby putting less pressure on prices.

10. In response to a question from Congressman Lance Gooden, you pointed to a real-world example of two duplicative patents with only a one-word difference: the word "directly." Please provide identifying information for both patents and provide any additional context regarding this example that you think would be helpful to the Subcommittee.

The two patents are U.S. 8,940,878 and U.S. 9,643,997, they are linked together through a terminal disclaimer. Each contains two independent claims, as shown in the table below. The sections highlighted in blue are identical across both patents, while the portions highlighted in yellow appear in the dependent claims. In other words, the blue and yellow text is word-for-word the same in the claim sets of both patents. The only difference is a single word, "directly", which is shown in bold red in independent claim 7 of patent US'878.

US8940878 claims 1 and 7	US9643997 claims 1, 9 and 20
1. A method of purifying a protein expressed in a non-native soluble form in a non-mammalian expression system comprising: (a) lysing a non-mammalian cell in which the protein is expressed in a non-native soluble form to generate a cell lysate; (b) contacting the cell lysate with a separation matrix under conditions suitable for the protein to associate with the separation matrix; (c) washing the separation matrix; and (d) eluting the protein from the separation matrix, wherein the separation matrix is an affinity resin selected from the group consisting of Protein A, Protein G and a synthetic mimetic affinity resin.	1. A method of purifying a protein expressed in a non-native soluble form in a non-mammalian expression system comprising: (a) lysing a non-mammalian cell in which the protein is expressed in a non-native soluble form to generate a cell lysate; (b) contacting the cell lysate with a separation matrix under conditions suitable for the protein to associate with the separation matrix; (c) washing the separation matrix; and (d) eluting the protein from the separation matrix. ****** **20.** The method of claim 9, wherein the separation matrix is: (i) an affinity resin, selected from the group consisting of Protein A, Protein G, and synthetic mimetic affinity resin; or (ii) a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin. claim 9
7. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising: (a) expressing a protein in a non-native limited solubility form in a non-mammalian cell; (b) lysing a non-mammalian cell; (c) solubilizing the expressed protein in a solubilization solution comprising one or more of the following: (i) a denaturant; (ii) a reductant; and (iii) a surfactant;	9. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising: (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following: (i) a denaturant; (ii) a reductant; and (iii) a surfactant;

(d) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following: (i) a denaturant; (ii) an aggregation suppressor; (iii) a protein stabilizer; and (iv) a redox component; (e) **directly** applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix; (f) washing the separation matrix; and (g) eluting the protein from the separation matrix, wherein the separation matrix is a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.	(b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following: (i) a denaturant; (ii) an aggregation suppressor; (iii) a protein stabilizer; and (iv) a redox component; (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix; (d) washing the separation matrix; and (e) eluting the protein from the separation matrix. **20.** The method of claim 9, wherein the separation matrix is: (i) an affinity resin, selected from the group consisting of Protein A, Protein G, and synthetic mimetic affinity resin; or (ii) a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.

Two biosimilar applicants, Kashiv Biosciences and Fresenius Kabi, filed inter partes review (IPR) petitions challenging U.S. Patent No. 9,643,997 in March and June 2019, respectively. The PTAB instituted both petitions approximately six months later. In Fresenius Kabi's case, the PTAB found there was a reasonable likelihood that Fresenius Kabi would prevail on its argument that the challenged claims were anticipated by the prior art. Anticipation means that the claimed invention is not new because it was already disclosed in the prior art. In my testimony, I stated that the patent had been cancelled because it was shown to not be new. I appreciate the opportunity to clarify the record. In fact, Fresenius Kabi settled its IPR in June 2020 during the pre-litigation "patent dance" process under the BPCIA, before the PTAB issued a final written decision. Kashiv Biosciences settled its IPR in December 2019.

The reason I mentioned these two patents in my testimony is they illustrate the principle that each patent must be challenged individually before a biosimilar can enter the market risk-free. Under current U.S. patent practice, even a single-word difference, such as the addition or deletion of "directly," can support the issuance of a second patent, provided the patent owner files a terminal disclaimer. As a result, a challenger cannot rely on a court's invalidation of the first patent to invalidate the second. Instead, the second patent must be litigated separately.

For example, if a court concludes that the first patent is invalid because every element of its claims was already known in the prior art, much of that same analysis would need to be repeated for the second patent. In addition, the court would have to determine how the word "directly" should be interpreted. Thus, despite the claims being nearly identical, the second patent requires a separate challenge.

11. In response to a question from Chairman Darrell Issa, you referenced 2026 data showing that over the last 10 years, the average time it took for biosimilars to reach the market and begin competing with brand-name biologics was 18 years. Please provide this data to the Subcommittee along with a brief summary of its methodology.

The data I referenced are from the Association for Accessible Medicines (AAM), which analyzed the time between FDA approval of reference biologic products and the first commercial launch of a competing biosimilar in the United States. According to AAM's 2026 analysis, the average time to first biosimilar market entry over the last decade is **slightly more than 18 years** after approval of the reference biologic. AAM also notes that the earliest biosimilar entered the market only after just over 13 years.[27]

The methodology is straightforward. For each biologic that experienced biosimilar competition, AAM measured the elapsed time from the FDA approval date of the reference biologic to the date the first biosimilar was commercially launched in the United States. The average was then calculated across products that had experienced biosimilar entry during the study period.

This average of more than 18 years is significant because it substantially exceeds the exclusivity periods Congress established for biologic medicines. Under the Biologics Price Competition and Innovation Act (BPCIA), Congress provided biologics with **12 years of FDA regulatory exclusivity** before biosimilars could be approved. Separately, Congress capped patent term extension under the Hatch-Waxman Act so that a patent, as extended,

[27] https://accessiblemeds.org/resources/blog/ira-hurts-generic-biosimilar-medication-competition/

generally cannot provide more than **14 years of patent life following FDA approval**.

Taken together, these statutory provisions reflect Congress's judgment that innovators should receive a substantial but limited period of protection before competition begins. In practice, however, biosimilar competition is not occurring until more than 18 years after FDA approval on average—approximately six years after FDA exclusivity expires and four years beyond the maximum post-approval patent term extension contemplated by Congress. This gap demonstrates that factors beyond the exclusivity periods established by Congress, most notably the accumulation and enforcement of large patent thickets, are frequently delaying biosimilar competition well beyond the timeframe Congress envisioned.

12. In response to a question from Chairman Issa, you stated that the drug Symbravo holds five "unique" patents and 70 "duplicate" patents. Please provide peer-reviewed data supporting these claims and summarize the methodology used.

During my testimony, I stated that Symbravo has five unique patents and approximately 70 duplicate patents. I did not represent that these figures were derived from a peer-reviewed study. The figures are drawn from a recent empirical analysis conducted by **Generation Patient**, a patient advocacy organization led by young adults living with chronic illnesses, including one individual who uses Symbravo. The study is available here. A simple way to determine unique patents vs. terminally disclaimed continuation patents is to simply look up the patent on the USPTO website where there is a clear record of whether or not a patent is subject to a terminal disclaimer.

Methodology

Generation Patient reviewed the patents actually asserted by Axsome Therapeutics against Apotex and identified patents that had been linked through terminal disclaimers. Specifically, the researchers:

- Reviewed the terminal disclaimer request form for each terminally disclaimed patent asserted in the litigation;
- Assessed linkages between earlier-filed and later-filed terminally disclaimed patents; and
- Grouped together patents connected through those terminal disclaimer linkages into "patent groups"

Using this methodology, the researchers identified **five unique patents among 75 asserted patents**. The analysis is based on publicly available patent prosecution records and litigation filings.

13. In response to a question from Chairman Issa, you stated that "because the U.S. patent system is so volatile, American patients get access to cheaper drugs later, and less manufacturing can happen in the U.S." Please provide peer-reviewed data to support these claims and explain the methodology behind it. We are particularly interested in data directly supporting the claim that access delays or disparities in domestic manufacturing capacity are caused by volatility in the patent system.

Despite its large US-based manufacturing footprint for other products, Fresenius Kabi has limited U.S. biosimilar manufacturing despite having a robust pipeline that has the potential to save Medicare and patients millions of dollars each year. Biosimilar companies cannot "make, use, import or sell" biosimilars in the U.S. until the relevant patents are cleared.[28] Because of patent thickets and ancillary product patents, that do not exist in the EU, the U.S. is typically the last country where a biosimilar can be manufactured. This means that biosimilar manufacturers cannot launch their drugs in other countries as net exporters from the U.S. Even if a manufacturer does not sell a single dose of a biosimilar in the U.S. and solely exports to the EU, they would infringe relevant U.S. patents by making the biosimilar in the U.S.[29] The delayed launches of complex generics and biosimilars compared to the EU is due to anti-competitive U.S. patent strategies that keep U.S. patients paying more longer than in the EU.

To explain this disparity between the U.S. vs. EU patent systems, consider a case study that details Europe's low tolerance for anti-competitive patent thicket behavior vs. that of the U.S., a nation that claims to be the protector of free market forces.

Case Study: Copaxone

On October 31, 2024, the European Commission ruled in the Teva Copaxone case (Case AT.40588 – Teva Copaxone) and fined Teva EUR 462 million for abusing its market position, which included gaming the EU patent system. The Commission found that Teva inappropriately extended Copaxone's patent protection by misusing the European Patent Office (EPO) rules pertaining to so-called divisional patents. Divisional patents are based on an original invention, or inventive feature, but cover different or more narrow aspects of that invention. Although the EU does not allow terminal disclaimers, the

[28] https://www.law.cornell.edu/uscode/text/35/271?utm_source=chatgpt.com
[29] PatentThickets_May2021_FINAL.pdf

divisional practice is similar in that the patents are assessed separately but get the same expiry date of the parent patent. In comparison, terminal disclaimer practice in the US is proactively initiated by the patentee to amass large numbers of patents on non-distinct inventions.

The Copaxone patents in question were filed over eight years in Europe, between 2010 and 2018, with an attempt to multiply duplicative patents with significantly overlapping claims. In other words, Teva tried to replicate their U.S. patent strategy in Europe. The European Commission found that the claims in the divisional patents were not new and were based on the science already contained in the parent patent. The Commission fined Teva for anti-competitive behavior. In contrast, duplicative terminally disclaimed patents are entirely permitted in the U.S. In the U.S., there are over 15 times more patents against 30 biosimilars than in the Canada, and over seven times more patents against biosimilars than in the UK.[30]

Furthermore, the EU Commission found that Teva systematically withdrew various divisional patents just before a negative decision on their validity, thereby denying generic drug competitors the possibility to clear the path to market entry and avoiding legal precedents that could have undermined other divisional patents having overlapping patent claims. While the European Commission condemns such behavior as anti-competitive, this is standard practice in the U.S. These claims brought by the Commission against Teva are common practice and completely legal in the U.S. and have become standard in delaying lower-cost generic and biosimilar competition on the most expensive drugs in the market.

For example, terminally disclaimed patents make up a substantial amount of the patents asserted against biosimilars and they are filed and granted just before the end of the branded data exclusivity period.[31]

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[30] Goode R, Chao B. Biological patent thickets and delayed access to biosimilars, an American problem. J Law Biosci. 2022 Sep 1;9(2):lsac022. doi: 10.1093/jlb/lsac022. PMID: 36072417; PMCID: PMC9439849.

[31] Tu SS, Goode R, Feldman WB. Biologic Patent Thickets and Terminal Disclaimers. JAMA. 2024;331(4):355–357. doi:10.1001/jama.2023.25389

Thank you again, Chairman Issa and Ranking Member Johnson for including me in this important hearing. I remain available to help the Subcommittee make informed policy decisions that preserve innovation while promoting affordability to your constituents.

Sincerely,

Rachel Goode, JD, PhD

Rachel Goode

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