Anatomy of a Biosimilar Patent Litigation: Problems and Solutions

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Association for Accessible Medicines

BIOSIMILARS COUNCIL™
A DIVISION OF AAM

Accord BioPharma, Inc.
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I. EXECUTIVE SUMMARY

As rising prescription drug costs continue to threaten the U.S. healthcare system, it is more important than ever to increase patient access to more-affordable biosimilar versions of branded biologic medicines. But patent thickets, and the prohibitively complex, expensive and risky patent litigations they enable, are hobbling biosimilar competition and delaying public access to these vital, safe and effective lower-cost medicines. For example, thickets, not allowed in Europe and other developed nations, directly contribute to the U.S. paying more for drugs than other countries. [1] This delayed launch of biosimilars impacts domestic manufacturing of biosimilars, as making biosimilars in the U.S. for net export is prohibited by U.S. patent law.[2]

As we explain in this white paper, Congress needs to act to address these issues. The following patent reform would expedite biosimilar entry:

CAPPING THE NUMBER OF ASSERTED PATENTS: H.R. 3269

Brand manufacturers must be limited to a reasonable number of asserted patents in biologics patent litigation. **H.R. 3269, the ETHIC Act,** would also cap the number of patents in terminally-disclaimed families. That term refers to the fact that a terminal disclaimer has been filed by the brand company to overcome a rejection called obviousness-type double patenting, which is a patent law doctrine that precludes companies from obtaining patents that contain claims that are patentably indistinct from one another. The ETHIC Act helps ensure that only innovative patents will be asserted by brand companies and it prevents them from ceaselessly asserting patents that are obvious duplicates of one another. **S. 1041, the Affordable Prescriptions for Patients Act,** which is pending in the Senate, would cap the number of asserted patents in biologics patent litigation at 20 if certain criteria are met.

AVOIDING UNNCESSARY RESTRICTIONS ON PATENT SETTLEMENTS: S. 1096

Biosimilar manufacturers also must be free to settle time-consuming and expensive patent litigation in a procompetitive manner. **S. 1096, the Preserve Access to Affordable Generics and Biosimilars Act,** would delay biosimilar entry by creating a presumption that biosimilar patent settlements are anticompetitive based on outdated data from the Federal Trade Commission. Absent procompetitive settlements, patients will pay higher brand biologic prices for longer.

PROVIDING A STATUTORY SAFE HARBOR FOR LABELING CARVE-OUTS: S. 43

Congress should also provide a **statutory safe harbor for carve-outs of patented methods of treating diseases as set forth in S. 43, the Skinny Labels, Big Savings Act**. Biosimilar manufacturers routinely exclude—or "carve-out"—patented methods of treatment (such as, for example, a method of treating rheumatoid arthritis, from their labels when those methods of treatment are patented. Despite this well-established practice, the Federal Circuit has twice found that there can be liability for patent infringement despite a carve-out in ***GSK v. Teva*** and ***Amarin v. Hikma***.[3] Congress can address this incongruous result by providing for a statutory safe harbor for labeling carve-outs, which has been supported by Henry Waxman.

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[1] Rachel Goode & Bernard Chao, *Biological patent thickets and delayed access to biosimilars, an American problem*. J Law Biosci. (Sep. 1, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9439849/pdf/lsac022.pdf.

[2] A. Brill & C. Robinson, *How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing* (May 2021), https://getmga.com/wp-content/uploads/2022/04/PatentThickets_May2021_FINAL. pdf.

[3] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021); *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 104 F.4th 1370 (Fed. Cir. 2024).

In this white paper, we explain how biosimilar patent litigation works in practice, and how brand companies game the system by overwhelming U.S. courts with these thickets. Overburdened federal courts are poorly equipped to resolve these patent pile-ons quickly, inexpensively or fairly. Biosimilar manufacturers are left with the difficult choice of spending years and millions of dollars to challenge hundreds—or even thousands—of patent claims in court or waiting out the patents until they expire. Neither choice helps patients.

As we detail throughout this paper, patent thickets have become the latest tool that branded manufacturers use to weaponize the inefficiencies of the court system. Perhaps the most well-known example of this is Humira®. To further its goal of delaying biosimilar competition, AbbVie "applied for follow-on patents to Humira, withdrew the applications during the examination process, then applied for yet more follow-on patents, creating a moving target for its biosimilar rivals."[4] AbbVie also abused the patent system by obtaining dozens of overlapping and non-innovative patents to assert against biosimilars in patent litigation.[5] Cases like Humira® show just how much the odds are stacked against the biosimilar manufacturer—they must run the gamut and invalidate or design around all the brand patent claims. If even a single brand patent claim is found to be valid and infringed, that biosimilar manufacturer may be subject to an injunction that forecloses patient access to lower-cost medicine, even if they invalidated 99 other patents. Although many of these patents may be valuable and important, the sheer number of patents—and these increasingly frequent tactics by brand companies—make it nearly impossible.

To make matters even worse, completely prevailing in patent litigation does not mean the biosimilar applicant is insulated from future infringement allegations. Brand companies frequently continue to prosecute patents within the same family, leading to the issuance of new patents after the initial litigation is filed or even completed. Biosimilar applicants accordingly remain at risk of facing additional litigations over the same biosimilar product, further delaying patient access to biosimilar products.

Recent court decisions have made the situation more challenging. As detailed below, the Federal Circuit has made it substantially more difficult for generics and biosimilars to "carve out" (i.e., omit) information from labelling relating to secondary patents covering, for example, new uses of approved products or "indications." This problem is particularly pervasive in the biologics industry: it is increasingly common for brand products to have a large number of indications. Indeed, Keytruda® (pembrolizumab), which is projected to be the top-ranked biologic worldwide

[4] Peter Loftus & Denise Roland, *The Strategies AbbVie Employed to Protect Humira From Copycats*, WALL STREET J. (Oct. 16, 2018), https://www.wsj.com/articles/the-strategies-abbvie-employed-to-protect-humira-from-copycats-1539687601.
[5] *Id.*

with more than $27 billion sales in 2024,[6] has 21 separate approved indications.[7] A biosimilar manufacturer's inability to omit patented uses would effectively provide perpetual exclusivity to brand manufacturers.

Proposed legislation has also not helped expedite access. Biosimilar companies have entered into procompetitive settlement agreements to attempt to expedite access, but state and federal legislation has attempted to substantially curb these agreements. States like California have passed legislation making many settlements presumptively anticompetitive, and Congress is likewise considering enacting S. 1096, which would similarly make many settlements illegal. While California is subject to a preliminary injunction against enforcement, these types of laws limit biosimilar applicants' options when faced with complex litigation. The consequence of these laws is delayed biosimilar competition. As a result, patients lose.

Congress should enact meaningful reform now to address the significant hurdles that delay patient access to lower-cost biosimilars.

II. OVERVIEW OF BIOLOGICS AND PATENT THICKETS

a. What Are Biosimilars and Why Are They Important to the Healthcare System?

Biologics are the most important class of next-generation medicine emerging from the U.S. biotechnology boom. Biologics harness nature's own cellular machinery to precisely target the root cause of many of the most debilitating diseases, often far more effectively than conventional drugs. Over the past 20 years, biologics have brought hope to, and extended the lives of, millions of Americans with previously untreatable disorders.

But this medical revolution has come at a steep price. Biologics are among the most expensive medicines ever sold. Many of the most widely-prescribed biologics have annual net prices of $40,000 or more, including popular products like Humira®, Cimzia®, and Etanercept®, which treat inflammatory diseases like rheumatoid

[6] *See, e.g.*, Patrick Wingrove & Leroy Leo, *Merck raises 2024 profit forecast on surging sales of cancer drug Keytruda*, Reuters (Apr. 25, 2024), https://www.reuters.com/business/healthcare-pharmaceuticals/merck-raises-2024-profit-forecast-strong-cancer-hpv-drugs-sales-2024-04-25/#:~:text=Analysts%20are%20estimating%20sales%20of,the%20end%20of%20the%20decade.

[7] While Keytruda's "expanding list of cancer indications" has driven its revenue growth, "nearly 20 percent of the drug's revenue growth came from price increases, totaling $3.1 billion over six years." *See* Gregg Girvan, *The Impact of Merck's Price Increases for Keytruda on Pharmaceutical Innovation*, FREOPP (Oct. 21, 2022), https://freopp.org/the-impact-of-mercks-price-increases-for-keytruda-on-pharmaceutical-innovation/ (disclosing a price increase from $1,058.54 to a high of $1,265.19 between 2015 and 2021).

arthritis.[8] While biologics account for only 15%[9] of prescriptions in the U.S., they account for more than half[10] of prescription drug spending.

Biologics are also among the most lucrative medicines, some with annual global sales in the tens of billions of dollars. For example, Humira earned its maker AbbVie over $16 billion in net sales in the U.S. alone.[11] In fact, even though they accounted for only a small fraction of total prescriptions, more than half of the top-earning medicines in 2020 were biologics.[12]

As branded drug companies increasingly focus their R&D budgets on biologics in pursuit of greater efficacy and profitability, biologics' share of annual prescriptions—and prescription drug spending—is expected to skyrocket in the coming decades. Indeed, this shift to biologics is already happening. Between 1996 and 2000, 14% of new drug approvals in the US were biologics.[13] Between 2016 and 2020, this fraction had increased to 26%.[14]

Biosimilars are the key to reducing this potentially massive expense. A biosimilar is a biologic medicine that is "highly similar" to or "interchangeable" with an already-approved, branded medicine. Biosimilars are reviewed and approved by FDA to ensure that there are no clinically meaningful differences between them and the branded product they reference. They are substantially less costly than the branded product because the biosimilar manufacturer is entitled to rely on the safety and efficacy data of the branded product, which both accelerates and lowers the cost of FDA approval. And when more than one biosimilar to the same branded product enters the market, prices drop even more dramatically. For example, it has been estimated that the market entry of the first biosimilar of infliximab in European countries resulted in a decrease of the volume-weighted average price per defined daily dose by an average of 13.6%, while the second biosimilar's market entry resulted in a decrease by 26.4%.[15] In view of the growth of

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[8] Victor Van de Wiele et al., *The characteristics of patents impacting availability of biosimilars*, 40 NATURE BIOTECHNOLOGY 22-25, 22 (Jan. 2022).

[9] *Competition in Prescription Drug Markets, 2017-2022*, ASSISTANT SECRETARY FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS. at 7 (Dec. 2023), https://aspe.hhs.gov/sites/default/files/documents/1aa9c46b849246ea53f2d69825a32ac8/competition-prescription-drug-markets.pdf.

[10] *The U.S. Generic & Biosimilar Medicines and Savings Report*, ASS'N FOR ACCESSIBLE MEDS. at 3 (Sept. 2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[11] *Drug Pricing Investigation AbbVie – Humira and Imbruvica*, STAFF OF HOUSE COMM. ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, 117TH CONG., at 4 (May 2021), https://oversightdemocrats.house.gov/sites/evo-subsites/democrats-oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf.

[12] Eric Sagonowsky, *The top 20 drugs by worldwide sales in 2020*, FIERCE PHARMA (May 3, 2021), https://www.fiercepharma.com/special-report/top-20-drugs-by-2020-sales.

[13] Van de Wiele, *supra* note 8, at 22.

[14] *Id.*

[15] Elif Car et al., *Biosimilar competition in European markets of TNF-alpha inhibitors: a comparative analysis of pricing, market share and utilization trends*, FRONT. PHARMACOL., at Abstract, (Apr. 20, 2023), https://pubmed.ncbi/nlm.nih.gov/37153785/.

biosimilar competition in Europe, it has been estimated that "[a]s of 2022, the cumulative savings at list prices from the impact of biosimilar competition in Europe reached over €30 billion."[16]

b. Brands Are Increasingly Assembling Large Estates of Patents

Patents are vital to U.S. leadership in biotechnology innovation, including biologic medicines. A patent may be granted for any useful, new and non-obvious invention. In exchange for a disclosure of how to make and use the invention, a patent gives the inventor the right to exclude others from making, using, selling or importing it for a limited term, usually 20 years from the filing date of the patent.[17] After the expiration of this patent term, the public is free to use the invention. This limited period of exclusivity provides a powerful economic incentive to innovate.

While an inventor is supposed to receive only one patent per invention, the U.S. patent system is very permissive compared to Europe and many other major economies.[18] It permits inventors to obtain "secondary" patents for "improvements" to ways of formulating, manufacturing, dosing or using an already-patented medicine. In fact, the United States Patent and Trademark Office grants more secondary patents than any other country.[19] Taking full advantage of this, manufacturers of branded medicines will almost always file for secondary patents as their original patents near expiry. A biosimilar may be forced to match at least some of these patented changes in order to be similar enough to the brand to obtain approval. Sometimes, these improvements are innovative and patentable. Other times, they are not.

And while U.S. patent examiners are supposed to guard against allowing secondary patents that are not sufficiently new and innovative, they are overburdened and have limited time and resources. These resource constraints mean that secondary patents are often allowed to issue when they do not meet patentability requirements. Post-grant review by the Patent Trial and Appeal Board has resulted in over 50% of reviewed biopharmaceutical-related patents being cancelled in whole or part because they did not meet patentability requirements.[20]

Overburdened patent examiners also cause many secondary patent terms to be extended for hundreds—or even thousands—of days. Although patents expire 20 years from the date of filing, a patentee is entitled to receive an extension to this patent term for any delays caused by the PTO during examination. Biologic patents are complex and examiners have huge dockets, so

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[16] *See* IQVIA White Paper, The Impact of Biosimilar Competition in Europe, at 5 (Dec. 2022), https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2022.pdf.

[17] Patents with an effective filing date earlier than June 8, 1995 are entitled to a patent term that is 17 years from the date of issuance. Patent term adjustments of hundreds—or even thousands—of days may be granted to compensate for patent office delays. For each new biologic approved by the FDA, one patent may be selected for a patent term extension to ensure that the product has at least 14 years of patent protection.

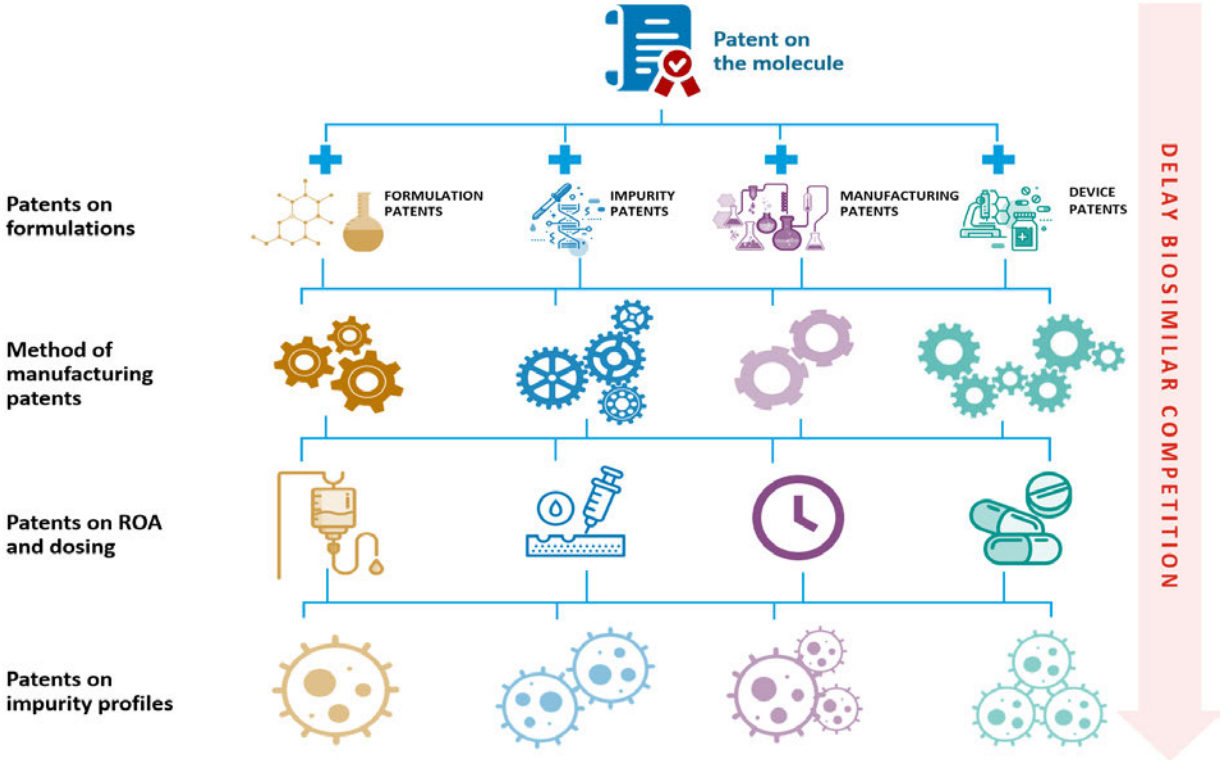
[18] *See* Van de Wiele, *supra* note 8, at 23 (explaining that "[a]mong patents asserted in US biosimilar litigation, . . . one-fifth of the patents had no equivalents—either patents or patent applications—in the [EU], Canada, or Japan").

[19] Bhaven N. Sampat & Kenneth C. Shadlen, *Secondary Pharmaceutical Patenting: A Global Perspective,* Working Paper 23114, NAT'L BUREAU OF ECON. RSCH. at Fig. 1 (Jan. 2017), https://www.nber.org/system/files/working_papers/w23114/w23114.pdf.

[20] *See, e.g.*, *PTAB Orange Book patent/biologic patent study*, USPTO FY24 Q2 at 18 (Mar. 31, 2023), https://www.uspto.gov/sites/default/files/documents/orange_book_biologics_study_march2024.pdf.

delays are very common. This means that secondary patents often issue with terms that are extended by many months or even years, which makes them even more attractive to brand manufacturers seeking to delay biosimilar competition.

Indeed, the wide variety of potential secondary patents are depicted below. As noted above, this can create a serious numbers game for biosimilar manufacturers:



The net result is that brand manufacturers have both the incentive and the ability to amass large numbers of weak, late-expiring secondary patents in the U.S. that a biosimilar manufacturer often cannot avoid, but instead must challenge in order to clear a path to market. It is unsurprising, then, that *brands have contested every single biosimilar launch in the U.S. with actual or threatened patent infringement litigation*. In other words, Congress painstakingly crafted a legal pathway to introduce competition and affordability into this expensive and growing market, yet brands have unanimously sought to roadblock the success of this pathway since inception.

As noted above, Humira® is, quite simply, the poster child for overpatenting in a manner that makes it impossible for biosimilars to "run the gamut." The case study below shows just how problematic those practices were.

AbbVie has obtained over 130 patents on Humira® that effectively extended its patent term from 2016 to 2034

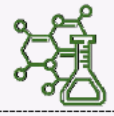
One glaring example is **AbbVie's Humira®.**

- Humira® was first **approved almost 20 years ago** and has improved the quality of life of many patients suffering from Crohn's Disease, rheumatoid arthritis and similar disorders.
- Humira®'s 12-year **statutory exclusivity expired in 2014** and its **original patent** to adalimumab, the biologic active ingredient, **expired in 2016.**
- Prior to the expiration of its patent to adalimumab, AbbVie filed a blizzard of patent applications that resulted in **more than 75 new patents** issuing just in time to assert against biosimilar manufacturers.
- All told, the patent thicket erected by AbbVie covered virtually every aspect of the medicine that a biosimilar might need to duplicate, including:

The **structure of adalimumab**, the active ingredient

Impurities of adalimumab

Formulations of adalimumab with commonly-used inactive ingredients

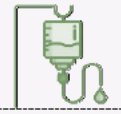


Highly-concentrated formulations of adalimumab

Methods of **genetically engineering cell cultures** to express adalimumab

Methods of **feeding cells with nutrients** to express adalimumab

Methods of **purifying adalimumab**, and adalimumab having varying degrees of purity



Methods of **administering adalimumab intravenously** or subcutaneously

Devices used to **administer adalimumab subcutaneously**

Dosage amounts and schedules used to treat patients

Methods of treating various diseases caused by inflammation, including rheumatoid, juvenile and psoriatic arthritis, inflammatory bowel disease, psoriasis and other skin disorders, and eye and spine inflammation.

Many of the patents contained overlapping and duplicative claims that were intended to make patent litigation prohibitively complex and expensive, in the hope that biosimilars would be dissuaded from challenging Humira® in the market.[21] A cap on the number of asserted patents would have represented meaningful reform for biosimilar manufacturers seeking to take on this enormous estate of patents.

More significantly, biosimilar manufacturers were able to enter the market and offer lower prices solely due to patent settlements. Indeed, biosimilar manufacturers settled for a July 2023 date—approximately 11 years before the expiration of AbbVie's patents and approximately five years after the first biosimilar launch of Humira® in Europe[22]—that ***would not have been possible absent settlements***.[23]

As the Federal Trade Commission itself has acknowledged, the days of so-called "reverse payments" are long gone—in its most recent report, the Federal Trade Commission found that the number of problematic patent settlements was "very low."[24]

III. ANATOMY OF A BIOSIMILAR PATENT LITIGATION

a. Far More Patents Are Asserted in the United States Than Other Countries

As a threshold matter, patent litigation in the United States is far different—and more complex—than other countries. A critical difference between the U.S. versus Canada and the U.K., where biosimilar access is far greater, is the sheer number of patents asserted in such litigation:[25]

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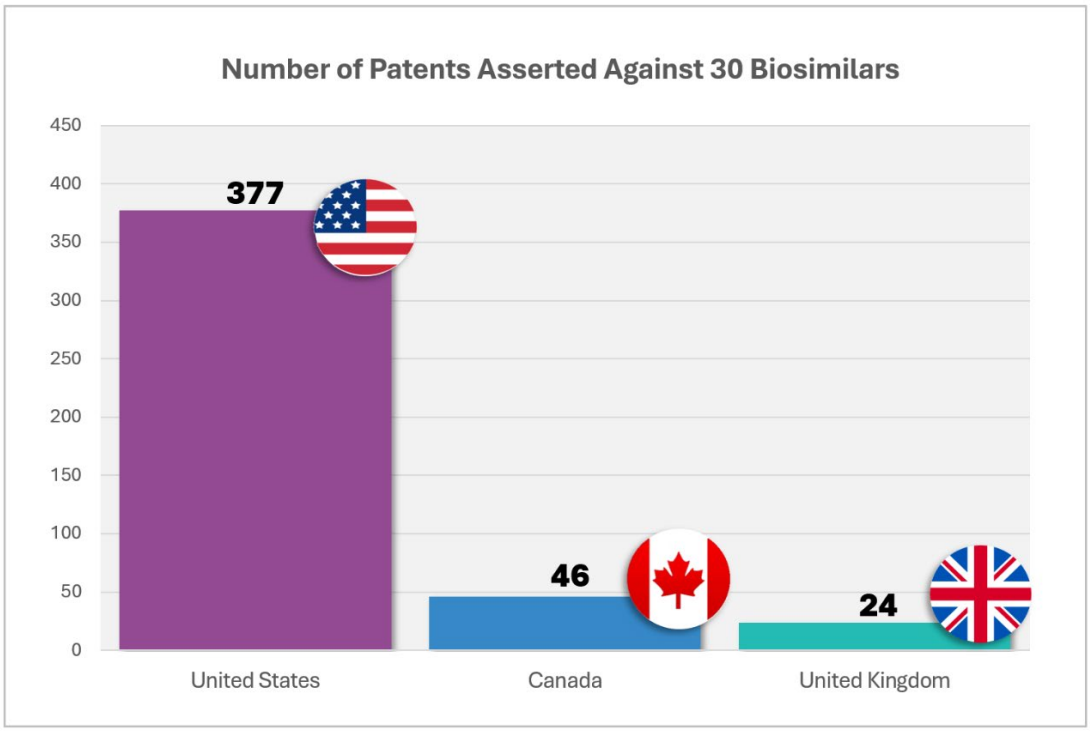
[21] *See, e.g.*, AAM, *Patent Settlements Are Necessary To Help Combat Patent Thickets*, https://accessiblemeds.org/resources/blog/patent-settlements-are-necessary-to-help-combat-patent-thickets/ (explaining that "external, peer-reviewed research has found that the Humira® patent estate is comprised of 80% duplicative patents").

[22] *See, e.g.*, Jill Coghlan et al., *Overview of Humira® biosimilars: current European landscape and future implications*, J Pharm Sci. 110(4): 1572–1582 at Abstract (April 2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8014989/pdf/nihms-1678621.pdf.

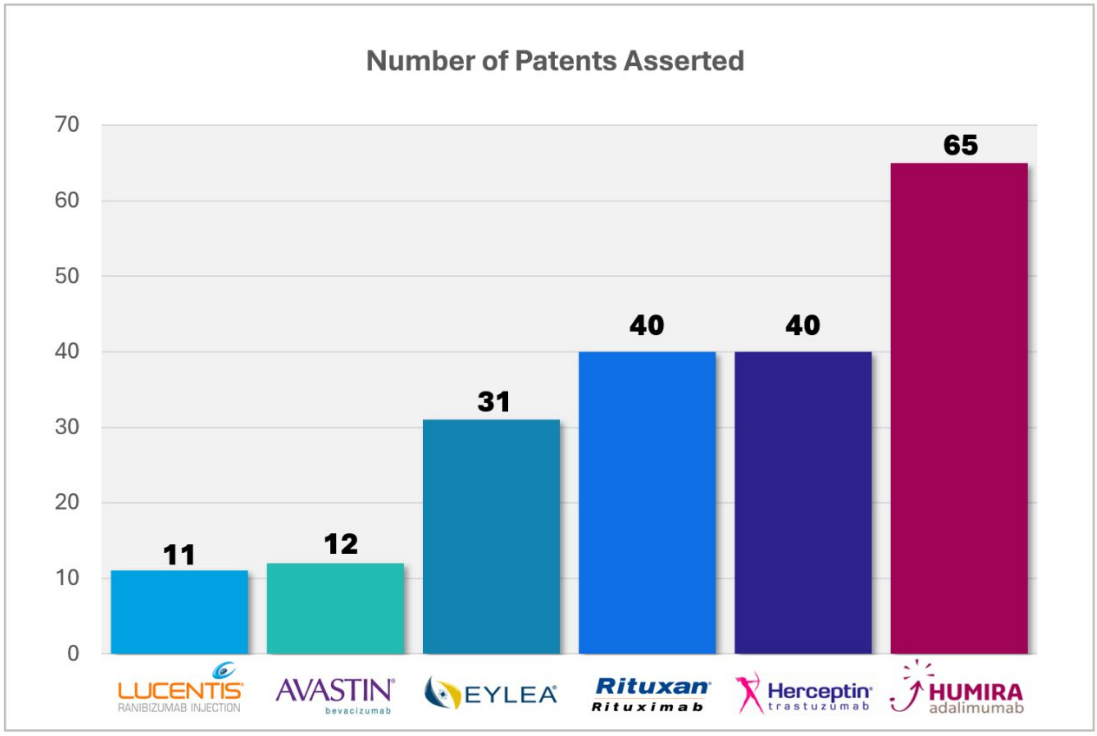
[23] Press Release, AbbVie, *AbbVie Announces Global Resolution of HUMIRA® (adalimumab) Patent Disputes with Samsung Bioepis* (April 5, 2018), https://news.abbvie.com/index.php?s=2429&item=123539.

[24] Press Release, FTC, *FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors: The number of reverse-payment agreements remains low; for the first time since FY 2004, no agreement contains a no-AG commitment* (Dec. 3, 2020), https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent-settlements-generic-competitors.

[25] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, An American Problem*, 9 J. Law and the Biosciences 1, 5 (Sept. 1, 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4014760.



By contrast, data collected by FDA and court filings shows that for six recently-approved biosimilars in the United States, the brands asserted between 11 and 65 patents *per product*:[26]



[26] FDA PURPLE BOOK DATABASE OF LICENSED BIOLOGICAL PRODUCTS, https://purplebooksearch.fda.gov/patent-list.

Studies help clarify why so many more patents are asserted in the United States. Indeed, a recent study of all U.S. patents asserted against biosimilars in the US between 2010 and August 2020 made clear that the large majority are secondary patents that post-date the approval of the brand biologics license application: only 17% of the asserted patents were filed prior to approval of the branded biologic, and most were patents directed to manufacturing processes or preparations of the biologics at issue.[27] Simply stated, these patent thickets delay biosimilar competition because of their sheer size—because so many are owned and asserted, not all can be economically challenged.

Even before biosimilar litigation commences, large patent estates thwart competition by requiring extensive freedom to operate challenges. Biosimilar companies must "clear the decks" to compete with biologics without patent liability, and particularly when faced with large patent estates, must expend significant resources assessing such patents during development. In many cases, such patent landscaping analyses require time-consuming design around strategies and significant legal costs. Freedom to operate exercises are further complicated when biologics engage in serial prosecution activity, such as in the Humira® example discussed above, where AbbVie continuously applied for new patent applications, "creating a moving target for its biosimilar rivals."[28]

A prime example of such serial prosecution activity concerns Regeneron's patent litigation against Amgen's Eylea biosimilar. The parties' litigation started on January 10, 2024, when Regeneron initially filed a patent infringement complaint against Amgen.[29] Regeneron subsequently moved for a preliminary injunction, asking the court to enjoin Amgen from launching its competing biosimilar product.[30] But the district court found Regeneron had "not shown a reasonable likelihood of success on the merits because Amgen has raised a substantial question of noninfringement based on the specific formulation of Amgen's proposed biosimilar product" and denied Regeneron's motion.[31] This decision was affirmed on appeal, with the Federal Circuit emphasizing the "undisputed fact that Amgen's [biosimilar] product does not contain a buffer separate from the VEGF antagonist," as required by the asserted claims.[32]

Amgen launched its biosimilar product following Regeneron's injunction loss at the district court, but its fight was far from over. While Amgen was busy preparing for launch, Regeneron was busy seeking new claims to cover Amgen's product. One month after the district court denied Regeneron's preliminary injunction, Regeneron filed a new continuation patent application that this time did not require a buffer—the element that formed Amgen's non-infringement

[27] Van de Wiele, *supra* note 8, at 22.
[28] Peter Loftus & Denise Roland, *The Strategies AbbVie Employed to Protect Humira From Copycats*, WALL STREET J. (Oct. 16, 2018), https://www.wsj.com/articles/the-strategies-abbvie-employed-to-protect-humira-from-copycats-1539687601.
[29] Complaint, *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 2:24-cv-00264 (N.D. Cal. Jan. 10, 2024), ECF No. 1.
[30] Motion, *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 1:24-cv-00039 (N.D.W.V. Jun. 7, 2024), ECF No. 180.
[31] Order at 2, *In re Aflibercept Patent Litig.*, MDL No. 1:24-MD-3103 (N.D.W.V. Sept. 23, 2024), ECF No. 352.
[32] *Regeneron Pharms., Inc. v. Amgen Inc.*, 130 F.4th 1372, 1384 (Fed. Cir. 2025).

defense.[33] The new patent issued on June 17, 2025—seven months after Amgen launched its biosimilar—leading Regeneron to file a new infringement suit against Amgen the very same day.[34]

Regeneron's serial prosecution activity illustrates the complexity of biosimilar litigation, but moreover, illustrates the need for Congress to act to protect patient access to lower-cost biosimilars. During prosecution of Regeneron's buffer-free patent, the examiner rejected the claims for obviousness-type double patenting over the original patent Regeneron had initially asserted against Amgen (along with several other patents).[35] Regeneron overcame this rejection, and thus obtained its patent, by filing a terminal disclaimer.[36] This is the very fact pattern that H.R. 3269 seeks to address—preventing patent holders from using multiple terminal disclaimers to obtain obvious variants of patents that can be serially litigated against biosimilars with no innovative value. Congress should enact H.R. 3269 to block patent holders from engaging in similar gamesmanship.

b. Biosimilar Litigations Are Extremely Expensive and Time-Consuming

To understand the complexity of a biosimilar patent litigation, it helps to start with some baseline numbers. On average, a patent litigation takes about 3 years to complete and costs roughly $3 million *per patent*.[37] Appeals by the brand can tack on an additional 1-2 years and require an additional substantial investment. For example, as illustrated below, Amgen's patent litigation against Sandoz's filgrastim biosimilar product spanned ***nearly five years***, even though that case was resolved before trial, noninfringement was clear, and the case involved only two patents.[38]

To get a sense of why biosimilar patent infringement litigation takes so long and costs so much, consider what actually happens in the litigation and the years these various steps take to occur:

[33] *See* U.S. Patent No. 12,331,099.
[34] Complaint, *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 2:25-cv-5499 (N.D. Cal. Jun. 17, 2025), ECF No. 1.
[35] Non-Final Rejection, U.S. Appl. No. 18/924,707 (Nov. 29, 2024).
[36] Terminal Disclaimer, U.S. Appl. No. 18/924,707 (Jan. 30, 2025).
[37] Anne S. Layne-Farrar, *The Cost of Doubling Up: An Economic Assessment of Duplication in PTAB Proceedings and Patent Infringement Litigation*, 10 Landslide 1, 1-2 (May-June 2018), http://bit.ly/2JIDVVV.
[38] *See Amgen Inc. v. Sandoz Inc.*, 295 F. Supp.3d 1062 (N.D. Cal. 2017), *aff'd*, 923 F.3d 1023 (Fed. Cir. 2019); *see also* Complaint, *Amgen Inc. v. Sandoz Inc.*, No. 3:14-cv-04741 (N.D. Cal. Oct. 24, 2014), ECF No. 1.

An eight-month "patent dance" precedes the litigation. Biosimilar litigations start off with a complex, 8-month pre-suit procedure known as the "patent dance." The biosimilar applicant discloses its FDA application, and the brand discloses a list of every single patent it owns or licenses that it might assert. The biosimilar must then answer with detailed written explanations for why it does not infringe every single claim in the list, or why the claims are invalid. These explanations can be thousands of pages long. Although the dance is optional, some companies utilize it to help get certainty on potential asserted patents.

Suit must be filed in federal district court. These courts hear both civil and criminal actions, have extremely busy dockets, and often have severe resource constraints. It can take 6 months to simply get a case schedule, and years before a trial can be held.

There is no limit to the number of patents a brand may assert. A brand may bring suit on all of the patents it listed during the patent dance, which often amounts to all of the patents it has accrued for a biologic. The brand may also amend its case to add patents that the PTO issues during the lawsuit, and that it in-licenses from other companies before or during the suit.

The burden of proof is stacked against the biosimilar manufacturer. By law, the district court presumes that even the weakest secondary patent is valid and requires the biosimilar defendant to prove unpatentability under a much higher standard than the PTO uses.

Lengthy claim construction is required. Patent claims are often intentionally worded somewhat vaguely, to make it easier to stretch them to cover as many biosimilars as possible. In this phase, the parties brief and argue disputes over the meaning of claim terms, often using expert witnesses to explain how technical words are commonly understood. For cases involving hundreds or thousands of claims, there are usually many disputes to be resolved.

Fact discovery phase is burdensome and expensive. The parties exchange evidence relating to infringement and validity of the patent claims, and sometimes damages and injunctions. This typically involves:

- Millions of pages of documents
- Several dozen depositions of witnesses;
- Thousands of pages of written questions and answers;
- Dozens of motions to the court to resolve disputes over discovery.

Expert discovery phase is highly complex. Biosimilar litigation usually involves highly complex biotechnology and each side hires a team of experts to explain the technical evidence to the court and/or jury. Each writes one or more reports and sits for one or more depositions. Sometimes experts also conduct experiments to prove (or disprove) aspects of the case. Dozens of experts can be involved, and the reports can total thousands of pages.

Trial is risky and expensive. At trial, the parties present their cases through the testimony of fact and expert witnesses. In cases where a biosimilar has launched its product and the brand has demanded that it be paid damages, the trial may involve a jury, which may struggle to understand complex biotechnology or patent law. Trials are extremely complex and expensive undertakings, often costing millions of dollars in fees and expenses. They are also risky for a biosimilar, which must defeat *all* claims in order to clear a path to market.

Injunctions: The biosimilar applicant must give six months' prior notice to the brand that it intends to launch the biosimilar; thereafter, the brand may seek a preliminary injunction, which is an order that forbids the biosimilar from launching until after the court issues its final judgment. After trial, if the biosimilar applicant is found to infringe even a single patent claim, the brand plaintiff may be entitled to an injunction barring the biosimilar from launching its product until the patent expires.

Damages: Patentees are entitled to whatever lost profits they can prove from any infringement, but no less than a reasonable royalty. Since the annual net U.S. profits for a branded biologic often stretch to billions of dollars, many biosimilar companies are reluctant to launch their products before a patent dispute is finally decided and risk having to pay damages.

Appeal: In almost every instance in which a biosimilar prevails at trial, the brand files an appeal. The U.S. Court of Appeals for the Federal Circuit, which hears all appeals from patent cases, regularly disagrees with district courts and overturns their judgments with some frequency. Given the risk of damages, biosimilar applicants that win at trial may choose to wait the additional 1.5-2 years it takes to resolve an appeal before launching.

Adding more patents to a case makes each of the above phases more complex, which adds to the expense and time needed to resolve the case. Piling on patents also make litigation riskier for the biosimilar, since losing on even one patent claim means the biosimilar must wait until the patent expires before it can go to market.

c. Legislative Proposals Around Patent Settlements Have Further Complicated Biosimilar Patent Litigation

Given the cost, delay and risk of litigating huge thickets of secondary patents, biosimilar manufacturers often agree to settle cases before trial. But state and federal law has severely constrained the terms of biosimilar (and other pharmaceutical) patent settlements. By way of example, California passed a statute, AB 824, aimed at deterring drug companies from entering settlements by categorizing many settlements as presumptively anticompetitive.[39] Statutes such as these stifle settlements and have caused parties to pull out of settlement discussions due to

[39] *See* Preserving Access to Affordable Drugs, A.B. 824 (Cal. 2019).

concerns they will be accused of a violation.[40] In the face of such laws, biosimilars are essentially limited to the choice of litigating for years all the way through appeal or agreeing to stay off the market for some or most of the term of the secondary patents. Either way, brands end up delaying biosimilar launch and patients lose out.

Making matters worse, patent settlement legislation is unwarranted in view of the FTC's own data on patent settlements. According to the FTC's statistics, by 2016, patent settlement agreements using the types of terms the Supreme Court deemed problematic in *FTC v. Actavis* "decline[d] to [the] lowest level in 15 years."[41] As the FTC conceded, "[t]he data are clear: the Supreme Court's Actavis decision has significantly reduced the kinds of reverse payment agreements that are most likely to impede generic entry and harm consumers."[42] The FTC made similar findings the following year, recognizing that, "[d]espite the high number of settlements, those that include the types of reverse payments that are likely to be anticompetitive remain very low."[43]

A recent report by the Association for Accessible Medicines and its Biosimilars Council illustrates the immense value patent settlements provide to patients. Since the *FTC v. Actavis* decision in 2013, the IQVIA Institute for Human Data Science conservatively estimated that patent settlements have saved the healthcare system ***$423 billion***.[44] In particular, the IQVIA Institute analyzed 288 molecules and identified 84 molecules with patent settlements.[45] These patent settlements resulted in an average generic or biosimilar market entry that was 64 months before patent expiry, providing an average five billion dollars in savings per molecule.[46] In fact, one such molecule—teriflunomide—was the subject of a patent settlement that resulted in over $1.1 billion in 2023 alone.[47] Because the patent settlement for this molecule allowed generic entry 11 years prior to patent expiry, such savings will accrue for over a decade.[48]

As this data and the Humira® example makes clear—where patent settlements allowed biosimilars to enter the market over a decade before patent expiry—patent settlements are

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[40] *See Ass'n Accesible Meds. v. Bonta*, No. 2:20-cv-01708, 2022 WL 463313, at *3 (E.D. Cal. Feb. 15, 2022).

[41] Press Release, FTC, *FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors: Reverse-payment agreements using side deals and no-AG commitments decline to lowest level in 15 years* (May 23, 2019), https://www.ftc.gov/news-events/news/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent-settlements-generic-competitors.

[42] *Id.*

[43] Press Release, FTC, *FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors: The number of reverse-payment agreements remains low; for the first time since FY 2004, no agreement contains a no-AG commitment* (Dec. 3, 2020), https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent-settlements-generic-competitors.

[44] AAM, *Generic and Biosimilar Patent Settlements Save $423 Billion* (June 3, 2025), https://accessiblemeds.org/resources/press-releases/generic-and-biosimilar-patent-settlements-save-423-billion/.

[45] AAM, *$423B Savings from Patent Settlements Since Actavis Ruling* (June 3, 2025), https://accessiblemeds.org/resources/blog/423b-savings-from-patent-settlements-since-actavis-ruling/.

[46] *Assessment of the Impact of Settlements*, ASS'N FOR ACCESSIBLE MEDS. at 5-7 (June 2025), https://accessiblemeds.org/wp-content/uploads/2025/06/202506-AAM-Impact-of-Patent-Settlements-IQVIA-Study.pdf.

[47] *Id.* at 4.

[48] *Id.*

important tools that can promote competition and lift barriers to market entry.[49] Despite the clear savings afforded by patent settlements, some proposed legislation, such as S. 1096, would "have a chilling effect on settlements—and consequently on the effective reduction of healthcare costs arising from such settlements."[50] Such legislation would likewise " serve to only worsen the brand leverage issue even further by limiting the terms that generics and biosimilars can obtain in patent settlements."[51] State and federal patent settlement legislation ignore the procompetitive realities of patent settlements like the Humira® example and deter biosimilar manufacturers from settling patent litigation.

d. The Ability to Do Labeling "Carve-Outs" is Under Question

Complicating matters even further is a lack of clarity surrounding labelling carve-outs, which are unquestionably necessary to expedite patient access to lower-cost biosimilars. Absent clear authority with respect to those carve-outs, patient access will certainly be delayed.

Since the enactment of the Hatch-Waxman Act in 1984, generic drug manufacturers have brought numerous generic drugs to the market via the "skinny labeling" mechanism that "carves-out" brand drug sponsors' patented methods of use from their FDA-approved labeling. This "carve-out" is frequently referred to as a "section viii" statement, which is a reference to the relevant provision of the Federal Food, Drug, and Cosmetic Act. Biosimilar manufacturers are also able to carve-out of their labeling brand manufacturers' patented methods of use.

For example, if a brand is approved for four different diseases, one of which is covered by a patent, biosimilar manufacturers can "carve-out" that patented method of use, gain FDA approval for the remaining three diseases, and bring to the market a more affordable alternative. This "carve-out" process has served the public interest for over 40 years by increasing access to generic medicines, and saves the healthcare system billions of dollars. And the rationale for carving-out patented indications is straightforward: competition is facilitated on unpatented uses of brand products and patients are able to have timely access to more affordable medicine. As the Supreme Court has rightly recognized, Congress provided for carve-outs so "that one patented use will not foreclose marketing a generic drug for other unpatented ones."[52]

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[49] Press Release, AbbVie, *AbbVie Announces Global Resolution of HUMIRA® (adalimumab) Patent Disputes with Samsung Bioepis* (April 5, 2018), https://news.abbvie.com/index.php?s=2429&item=123539.

[50] AAM, *$423B Savings from Patent Settlements Since Actavis Ruling*, https://accessiblemeds.org/resources/blog/423b-savings-from-patent-settlements-since-actavis-ruling/.

[51] AAM, *Patent Settlements Are Necessary To Help Combat Patent Thickets*, https://accessiblemeds.org/resources/blog/patent-settlements-are-necessary-to-help-combat-patent-thickets/ (explaining that "external, peer-reviewed research has found that the Humira® patent estate is comprised of 80% duplicative patents").

[52] *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012).

> Uncertainty about the section viii pathway is likely to deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design.
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> **Brief of Solicitor General at 13, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC,* No. 22-37 (Mar. 29, 2023)**

Despite the well-established "carve-out" practice, the U.S. Court of Appeals for the Federal Circuit, in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 25 F.4th 949 (Fed. Cir. 2022), concluded that there was substantial evidence of patent infringement (i.e., induced infringement) even though Teva's generic drug label for carvedilol contained, for three years, the very type of carve-out that is contemplated in Hatch-Waxman. As Judge Prost stated in her dissent: "Teva did everything right" in the case.[53] It submitted a "skinny label" that carved-out Glaxo's patented method of treatment and left only unpatented methods on the generic label from 2008-2011.[54] It took "care not to encourage infringing uses" when it launched its low-cost, therapeutically equivalent generic alternative to Glaxo's Coreg® in 2007.[55] And it "proceed[ed] precisely as Congress contemplated."[56] Despite these facts, the Federal Circuit reinstated a jury verdict of $234 million in favor of Glaxo. As Judge Prost recognized, the majority decision "nullifies" Hatch-Waxman's provisions for skinny labels and "discourages generics from entering the market in the first place."[57]

Although biological products are not specifically governed by the Hatch-Waxman Act, FDA follows a similar carve-out practice with respect to biosimilars, and they are similarly subject to inducement claims by brand manufacturers on secondary method of use patents. Thus, just as the *Glaxo v. Teva* decision has affected how generic drug manufacturers pursue generic drugs and how brand drug manufacturers are viewing litigation as a means to thwart patient access to treatments that have been on the market through the "skinny label" pathway for years, the decision affects biosimilar and brand biologic manufactures in parallel ways.

[53] *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 976 F.3d 1347, 1373 (Fed. Cir. 2020) (Prost, J. dissenting), *vacated and replaced by* 25 F.4th 949 (Fed. Cir. 2022).
[54] *Id.*
[55] *Id.*
[56] *Id.* at 1361.
[57] *Id.* at 1365.

IV. SOLUTIONS

Given their effectiveness at delaying biosimilar competition, patent thickets will continue to be the norm unless action is taken to limit gamesmanship and promote efficient, timely resolution of legitimate patent disputes. Specific actions should include the following:

- ***Capping the Number of Asserted Patents to allow for assertion of one patent per non-distinct group:*** Given the sheer number of patents that brands own, it is reasonable to cap the number of patents that can be asserted by the brand in biologics patent litigation. This enables brands to "pick their best weapons" and courts to resolve these cases efficiently. Exemplary reform is included in **H.R. 3269**, **the ETHIC Act,** which restricts brands to a single patent out of a terminally-disclaimed family. This ensures that brands cannot interminably continue to assert obvious variants of the same patent claims against generic and biosimilar manufacturers.
- ***Permitting Procompetitive Patent Settlements*:** The Senate is currently considering legislation, **S. 1096**, that would make it extraordinarily difficult to settle patent litigation. Absent the ability to settle patent litigation, biosimilar manufacturers would be disincentivized to take on the extraordinary cost and burden of challenging brand patents and investing the $100-$300M required to develop biosimilars. The necessity of patent settlements is best illustrated by the case study of Humira® above, where patent settlements expedited biosimilar entry by ***11 years***. Moreover, S. 1096 – and its civil penalty provisions in particular – are likely at risk of being determined unconstitutional considering the U.S. Supreme Court's recent decision in *SEC v. Jarkesy*, 144 S. Ct. 2117 (2024). In that case, the Court ruled that a government agency "may not impose fines to penalize securities in its administrative proceedings because that practice violates the Seventh Amendment 'right of trial by jury' in all 'suits at common law.'" S. 1096 includes the exact type of claims the Supreme Court held are subject to Seventh Amendment protection. Further, reforming patent quality issues, such as terminal disclaimer practice, would rebalance the stifling leverage originators have over biosimilar manufacturers and should result in more balanced settlement terms.

- ***Provide a Statutory Safe Harbor for Labeling Carve-outs:*** As noted above, Congress should enact **S. 43, the Skinny Labels, Big Savings Act**, that provides statutory safe harbor for carve-outs of patented methods of treating diseases to address the fallout from the Federal Circuit's decision in *GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc*. and *Amarin v. Hikma*.

V. CONCLUSION

Large biologics patent estates delay biosimilar entry on expensive brand-name drugs. Congress can enact meaningful reform now that would represent positive change in this area, while also respecting the rights of patent holders.