Serial Patent Litigation White Paper

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Association for Accessible Medicines

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I. Executive Summary

Congressional action is needed to address serial patent litigation—a problem plaguing the pharmaceutical industry, delaying generic competition, and inflating drug prices. Over 40 years ago, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) seeking to strike "a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."[1] The Hatch-Waxman Act set forth a framework to achieve that goal, including a process for brand and generic companies to litigate patent disputes before generic drugs entered the market. But brand pharmaceutical companies have abused that framework, significantly shifting the balance in their favor through serial patent litigation. Amendments to the Hatch-Waxman Act are necessary to restore the balance that Congress intended.

Over the past two decades, brand pharmaceutical companies have increasingly weaponized Hatch-Waxman litigation through serial patent litigation. Serial patent litigation is a tactic used by brand pharmaceutical companies to seek multiple bites at the apple—repeatedly litigating patents over the same drug product and against the same generic company. In some instances, brand pharmaceutical companies have strategically asserted only a subset of their already-issued patents to maximize their chances of deterring competition. Under this scenario, brand companies may litigate patent infringement claims for years, then upon receiving an adverse judgment, raise new infringement claims against the same defendant from their collection of unasserted patents. In other instances, brand pharmaceutical companies may obtain new patents, including by utilizing continuation patents, that they can assert in a subsequent action. Such serial patenting is especially prevalent for secondary, non-compound, patents that cover other aspects of the relevant product, such as formulations, methods of treatment, impurities, and the like.[2] Brand pharmaceutical companies have brazenly admitted to seeking such patents for the specific purpose of capturing accused generic products.[3]

Regardless of whether serial patent litigation stems from existing or newly-obtained patents, the impact is significant. Serial patent litigation drives up litigation time and costs and materially increases the risk and uncertainty for generic companies.[4] Such protracted litigation is

[1] *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).

[2] Gupta, *One Product, Many Patents: Imperfect Intellectual Property Rights in the Pharmaceutical Industry* (Nov. 11, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3748158 (demonstrating that secondary patent rights can delay generic entry on average by three years, per secondary patent acquisition).

[3] *See, e.g.*, Amended Complaint at ¶ 32, *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129 (D.N.J. Apr. 6, 2018), ECF No. 66 (alleging that Allergan "obtained the new claims" with a different amount of claimed ingredients "specifically to address" Sandoz's noninfringement defense to prior patents).

[4] *See* Gregory Day et al., *Patent Law and the Emigration of Innovation*, 94 Wash. L. Rev. 119, 125 ("[T]he average cost to defend an infringement lawsuit in the United States is roughly $3.5 million."); American Intellectual Property Law Association, *2019 Report of the Economic Survey* (2019), https://www.ipwatchdog.com/wp-content/uploads/2021/08/AIPLA-Report-of-the-Economic-Survey-Relevant-Excerpts.pdf (reporting that the median litigation costs for

at odds with the Hatch-Waxman Act, which specifically contemplated resolution of patent issues within the statutory 30-month stay to provide "an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."[5] Worse, serial patent litigation impedes patient access to much-needed, lower-cost medications—a result at odds with Congress' intent to "speed the introduction of low-cost generic drugs to market."[6] As we illustrate in the case studies below, even after generic companies have prevailed in an initial litigation, serial patent litigation unfairly allows brand companies to block generic drugs from entering the market and continuously threaten generic companies with catastrophic monetary damages. The end result is less generic competition and higher costs for patients—all to the benefit of the brand company abusing the system.

Reforms are urgently needed to address and curb serial patent litigation tactics. Congress should amend the Hatch-Waxman Act to significantly narrow the circumstances when brand pharmaceutical companies can serially litigate patent infringement. By enacting legislation aimed at deterring serial patent litigation, Congress can restore its fundamental goal of promoting patient access to generic medications.

II. Patent Litigation Under The Hatch-Waxman Act

The Hatch-Waxman Act was enacted in 1984 to incentivize innovation in the development of new drugs while also promoting access to affordable generic alternatives to branded drugs. Under Hatch-Waxman, a company seeking to market a generic drug can obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA") demonstrating that the generic drug has the same active ingredient and is biologically equivalent to a brand-name drug. This process "speed[s] the introduction of low-cost generic drugs to market."[7]

Hatch-Waxman also "sought to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products."[8] This framework first requires brand pharmaceutical companies seeking approval for a brand-name drug to identify all patents which claim the drug or method of using such drug "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug."[9] That information is subsequently published in the FDA's

Hatch-Waxman patent infringement actions ranged from $900,000 to $5 million in 2019, depending on the amount at stake).

[5] *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (citing to 130 Cong. Rec. H9118 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman); 130 Cong. Rec. S10504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch)).

[6] *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

[7] *Id.*

[8] *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003).

[9] 21 U.S.C. §§ 355(b)(1); 21 C.F.R. §§ 314.53(b)(1), (c)(2).

"Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."[10]

Generic pharmaceutical companies seeking approval of an ANDA must then submit a "certification" with respect to each patent listed in the Orange Book in connection with the brand-name drug.[11] This can be done in multiple ways, including by simply certifying that there are no patents listed in the Orange Book or all listed patents will expire prior to the approval of the ANDA.[12] Alternatively, if the ANDA filer seeks FDA approval prior to the listed patent's expiration, it may submit a "Paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic drug.[13] The ANDA filer must also provide notice of the "Paragraph IV" certification to both the patent holder and the brand-name pharmaceutical company who owns the NDA for the product, who then have 45 days within which to file an infringement action.[14] If an infringement action is filed within this 45-day period, the FDA will automatically stay final approval of the ANDA for 30 months.[15] This 30-month stay is meant "to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market."[16]

If an ANDA filer is found to infringe one or more patents, the Hatch-Waxman Act identifies available remedies. A court can order that the ANDA product cannot be approved by the FDA until patent expiration and may further grant injunctive relief to prevent commercial manufacture or sale, among others.[17]

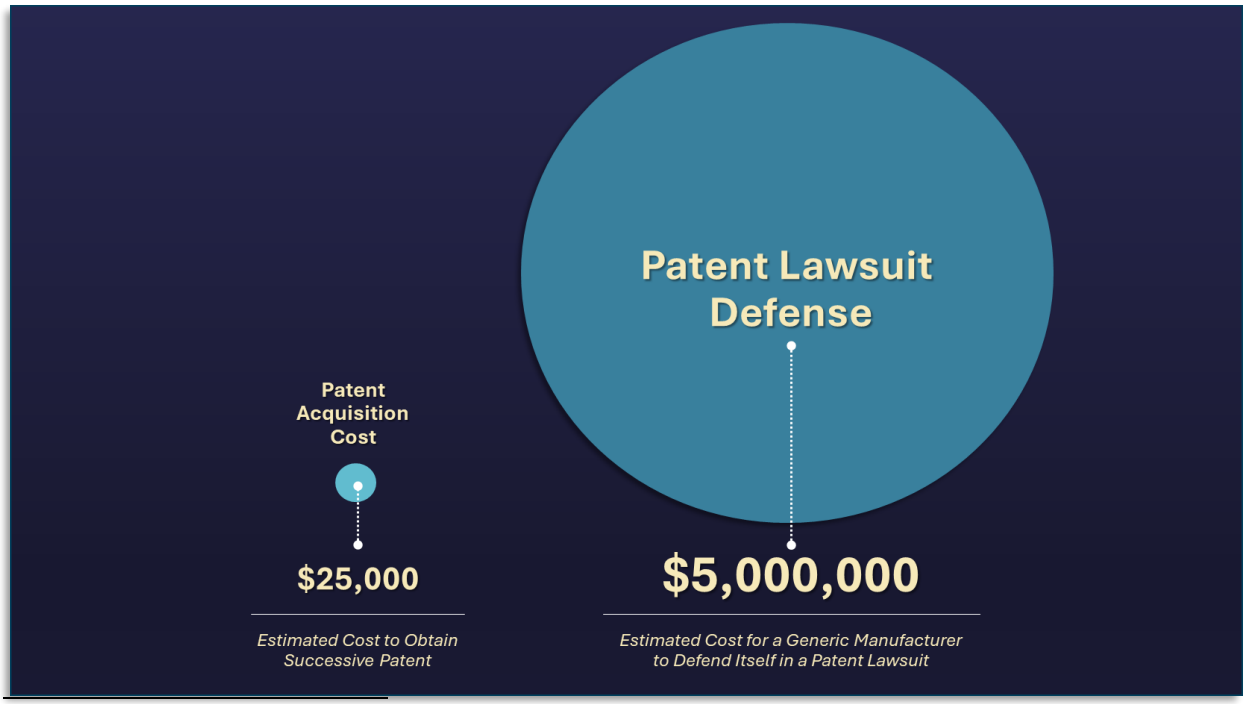
III. Implications of Serial Patent Litigation In Hatch-Waxman Cases

In view of the unique framework governing the Hatch-Waxman Act, serial patent litigation is a significant concern. Serial patent litigation has proliferated in recent years as branded companies have pursued additional ways to delay generic competition.[18] The dysfunction of

[10] 21 C.F.R. § 314.53(e).
[11] 21 U.S.C. §§ 355(j)(2)(A)(vii).
[12] 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III).
[13] 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV).
[14] 21 U.S.C. § 355(j)(2)(B).
[15] 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. 271(e)(2)(A).
[16] *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (citing to 130 Cong. Rec. H9118 (daily ed. Sept. 6, 1984) (statement of Rep. Waxman); 130 Cong. Rec. S10504 (daily ed. Aug. 10, 1984) (statement of Sen. Hatch)).
[17] 35 U.S.C. 271(e)(4).
[18] S. Sean Tu et al., *Changes in the Number of Continuation Patents on Drugs Approved by the FDA*, JAMA, Aug. 1, 2023, at 469–70 ("[T]he ratio of continuation patents increased 200% from 0.6 for drugs approved in 2000 to 1.8 for drugs approved in 2015 . . . These findings suggest that continuation patents are becoming increasingly common in drug patent thickets, likely delaying or deterring generic competition, and thus potentially contributing to delays in patient access to generic medications and increases in health care spending."); *see also* Rachael Robertson, *Continuation Patents Have Surged, Disrupting Generic Competition, Study Shows*, MedPage Today (Aug. 1, 2023), https://www.medpagetoday.com/special-reports/features/105720; *Csrxp: Analysis Finds 200 Percent Increase in Secondary Patent Filings as Big Pharma Exploits Loopholes To Block Competition*, The Campaign for Sustainable Rx

repeated, or serialized, litigation in Hatch-Waxman was recently acknowledged by the federal judiciary. Judge Andrews from the United States District Court of the District of Delaware has observed that, "the Hatch-Waxman process is designed to have an orderly process for resolving infringement questions before a generic is able to launch its product. The threat of repeat litigation is therefore at odds with at least one of the goals of the Hatch-Waxman process."[19]

The impact of serial patent litigation is staggering and solely benefits branded manufacturers. As it currently stands, brand manufacturers can trigger the 30-month stay under the Hatch-Waxman Act by asserting infringement of a subset of their Orange Book-listed patents, wholly knowing that it may assert one or more of its remaining patents against the same defendant at a later time. If such patents do not already exist, branded manufacturers typically can obtain serial patents easily and cheaply. According to one estimate, a successive patent may cost as little as $25,000 to obtain.[20] In contrast, according to now-dated estimates, the median cost for a generic manufacturer to defend itself in a patent lawsuit involving a single or small number of related patents is around $5 million.[21]



Pricing (Aug. 9, 2023), https://www.csrxp.org/csrxp-analysis-finds-200-percent-increase-in-secondary-patent-filings-as-big-pharma-exploits-loopholes-to-blockcompetition/.

[19] Order, *Exeltis USA, Inc v. Lupin Ltd.*, No. 1:22-cv-00434, (D. Del. Oct. 29, 2024), ECF No. 377.

[20] R. Goode & B. Chao, Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem, 9 J.L. & Biosciences, 19 (Sept. 2022).

[21] AIPLA Report of the Economic Survey 2019, *available at* https://www.ipwatchdog.com/wp-content/uploads/2021/08/AIPLA-Report-of-the-Economic-Survey-Relevant-Excerpts.pdf (reporting that the median litigation cost for a Hatch-Waxman litigation involving more than $25 million at risk is 5M USD); *see also* Gregory Day et al., Patent Law and the Emigration of Innovation, 94 Wash. L. Rev 119, 125 (2019) ("[T]he average cost to defendant an infringement lawsuit in the United States is roughly $3.5 million." We note that this average for a vanilla patent infringement lawsuit may underestimate how much it costs for a generic manufacturer to defend itself in a Hatch-Waxman litigation, which typically involves complex technologies and numerous experts.).

Where multiple waves of serial patent litigation are required, this can increase the cost by 2-3 times, or more. And litigation costs are only part of a generic's burden in bringing a product to market. A generic manufacturer will also face development costs of an estimated $1-5 million to develop a non-complex small molecule generic drug.[22] As can be seen, a generic manufacturer faced with serial patent litigation could require upfront investment costs of $20 million or more for a chance to bring a single product to market several years later, if ever. In comparison, the

> "Generic drug manufacturers face intense price competition, uncertain revenue streams, and high investment requirements to maintain mature manufacturing quality systems. These conditions incentivize reductions in manufacturing costs to potentially unsustainable levels, drive existing manufacturers out of the market, and deter potential market entrants—even when a drug is actively in shortage."
>
> **United States, Department of Health and Human Services. "Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States."**

market reality for generic companies is such that a generic manufacturer may only make tens of millions of dollars total on that same product. Thus, investing the upfront costs necessary to develop a product and endure multiple waves of serial patent litigation is often not financially viable for a generic company, especially given increased competition, lower margins, and lengthened timelines. Instead, a generic manufacturer may be incentivized to enter into a settlement agreement with the brand company and take a later launch date, rather than engaging in multiple and possibly never-ending, patent litigations.

Unfortunately, the current system lacks any consequences that would disincentivize branded manufacturers from serially litigating against generic filers on the same product. As Judge Andrews lamented, "[g]iven what I have seen in recent years, I am not as confident that a branded company, given the option of repeat litigation to protect its highly profitable branded product, would be deterred from that litigation simply because its chance of victory was poor."[23] To the contrary, serial patent litigation provides the branded manufacturer with multiple bites at the apple to obtain an injunction prohibiting generic launch, or monetary damages. With each subsequent litigation, the branded manufacturer also has opportunities to leverage the roadmaps created by prior litigation outcomes on, oftentimes, patents of similar scope, making it increasingly difficult, costly, and time-consuming for the generic filer to ultimately prevail.

[22] Federal Trade Commission, Emerging Health Care Issues: Follow-on Biologic Drug Competition (June 2009) (stating that product development costs for small-molecule generic drugs are "between $1 and $5 million").
[23] *Exeltis USA, Inc v. Lupin Ltd*., No. 22-cv-434-RGA, (D. Del. Oct. 29, 2024).

When generic and biosimilar competition is delayed, it has significant systemic costs. While generic and biosimilar medicines represent 90% of US prescriptions, they constitute just 13% of US prescription drug spending[24] and 1.2% of overall healthcare spending. And in 2023 alone, generic and biosimilar savings to the healthcare system totaled $445 billion, with savings over the last decade totaling $3.1 trillion.[25]

IV. Serial Patent Litigation Case Studies

Below are select real-world examples in which brand pharmaceutical companies have driven up litigation costs, lengthened the overall litigation timeline and increased the risk and uncertainty for generic pharmaceutical companies through the use of serial patent litigation.

A. BUPIVACAINE

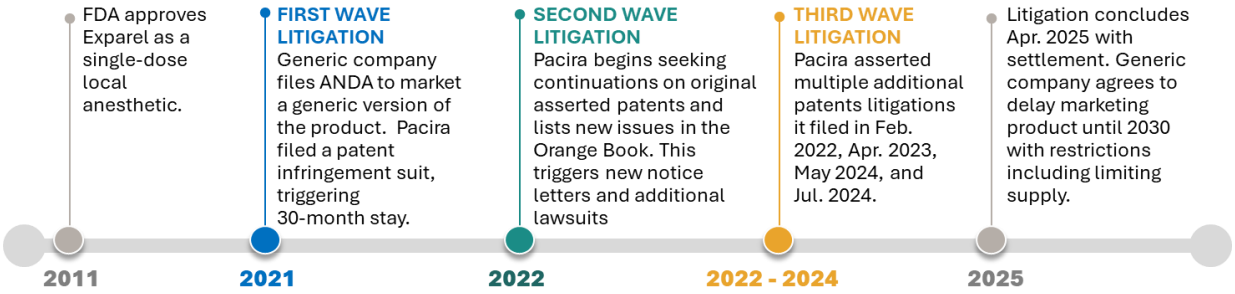
PACIRA

Pacira sought to protect its Exparel (bupivacaine) monopoly through serial patent litigation. Exparel is a single-dose local anesthetic administered at the time of surgery to control pain and reduce or eliminate the use of opioids for acute postsurgical pain. Ten years after Exparel was FDA-approved, in 2021, a generic company filed an ANDA seeking to market a generic version of the product. Pacira filed a patent infringement suit in November 2021, *Exparel I*, triggering the 30-month stay on approval of the generic product under the Hatch-Waxman Act.[26] That litigation concluded nearly three years later with a judgment of invalidity in the generic company's favor.[27]

Pacira appealed the district court's judgment of invalidity, but it did not stop there. Shortly after it filed its complaint in *Exparel I*, Pacira began seeking continuation patents of the patents it originally asserted. As those patents issued, Pacira listed the patents in the Orange Book, triggering additional notice letters and additional lawsuits. Before the district court issued a decision on the first wave of asserted patents, Pacira asserted multiple additional patents in four serial patent litigations it filed in February 2022, April 2023, May 2024, and July 2024.[28] What's more, after the district court issued a decision in the generic's favor, Pacira filed a sixth lawsuit—this time in an entirely new forum for a fresh bite at the apple.[29] The parties' litigation concluded in April 2025 due to a settlement in which—despite prevailing in *Exparel I*—the generic company

[24] Association for Accessible Medicines, The U.S. Generic and Biosimilar Medicines Savings Report, 2024 at 7, *available at* https://accessiblemeds.org/resources/blog/2024-savings-report.
[25] *Id.*
[26] Complaint, *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:21-cv-19829 (D.N.J. Nov. 8, 2021), ECF No. 1.
[27] Opinion, *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:21-cv-19829 (D.N.J. Aug. 9, 2024), ECF No. 403.
[28] Complaint, *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:22-cv-00718 (D.N.J. Feb. 10, 2022), ECF No. 1; Complaint, *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:23-cv-02367 (D.N.J. Apr. 28, 2023), ECF No. 1; Complaint, *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:24-cv-06294 (D.N.J. May 20, 2024), ECF No. 1; Complaint *Pacira Pharms., Inc. v. eVenus Pharms. Labs. Inc.*, No. 2:24-cv-07680 (D.N.J. Jul. 10, 2024), ECF No. 1.
[29] Complaint, *Pacira Pharms., Inc. v. Fresenius Kabi USA, LLC*, No. 1:24-cv-12416 (N.D. Ill. Dec. 3, 2024), ECF No. 1.

agreed to delay marketing its generic product until 2030, among other restrictions, including a limited supply.[30]



B. BIMATOPROST

Allergan

Over the span of approximately fifteen years (and counting), Allergan has initiated four waves of serial patent litigation concerning bimatoprost against the same generic companies. Latisse® (bimatoprost) is an Allergan ophthalmic solution indicated to treat eyelash hypotrichosis (i.e., hair loss or reduction of the eyelashes). Back in 2010, three generic pharmaceutical companies filed ANDAs seeking approval to market a generic version of Allergan's Latisse® (bimatoprost). Allergan promptly filed suit, triggering the 30-month stay under the Hatch-Waxman Act.[31] While the 30-month stay expired in January 2013, as of 2025, patent litigation over this product is ongoing.

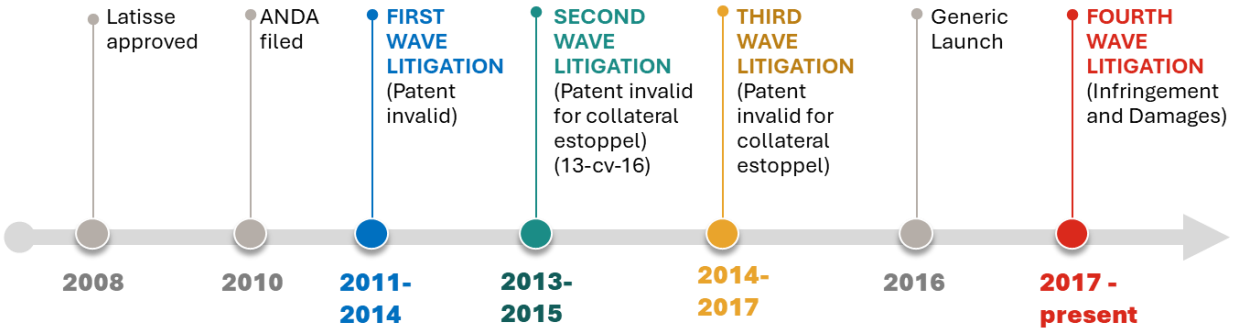
The first lawsuit, *Latisse I*, culminated in a 2014 decision from the Federal Circuit holding that Allergan's asserted patents were invalid.[32] Yet Allergan did not stop there. While that appeal was pending, Allergan initiated patent infringement proceedings against the same generic companies again. In that litigation, *Latisse II*, the district court held the newly-asserted patents were substantially the same as one of the patents invalidated under *Latisse I*, holding the patent invalid for the same reasons as in *Latisse I* and that Allergan was collaterally estopped from relitigating validity.[33]

The same year the Federal Circuit invalidated Allergan's patents in *Latisse I*, Allergan filed yet another patent infringement suit against the three generic companies.[34] This third litigation, *Latisse III*, stemmed from continuation patents that Allergan filed while the appeal was pending

[30] Pacira BioSciences Announces Settlement of U.S. Patent Litigation for EXPAREL (Apr. 7, 2025), *available at* https://www.biospace.com/press-releases/pacira-biosciences-announces-settlement-of-u-s-patent-litigation-for-exparel.
[31] *See, e.g.*, Complaint, *Allergan, Inc. v. Apotex, Inc.,* No. 1:10-cv-681 (M.D.N.C. Sept. 8, 2010), ECF No. 1.
[32] *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952 (Fed. Cir. 2014).
[33] Final Judgment, *Allergan, Inc. v. Apotex Inc.*, No. 1:12-cv-247, (M.D.N.C. Jan. 14, 2015), ECF No. 114; Final Judgment, *Allergan, Inc. v. Apotex Inc.*, No. 1:13-cv-16 (M.D.N.C. Jan. 14, 2015), ECF No. 77.
[34] First Amended Complaint, *Duke University v. Sandoz, Inc.*, No. 1:14-cv-01034-CCE-LPA (M.D.N.C. Jan. 9, 2015), ECF No. 15.

in *Latisse I*. The district court held, yet again, that Allergan's asserted patent was an obvious variant of those previously invalidated, invalidating the patent and holding Allergan was collaterally estopped from relitigating validity.[35] Allergan appealed the district court's judgment, and in 2017, the Federal Circuit affirmed collateral estoppel barred Allergan's infringement suit.[36]

In the meantime, one of the generic companies launched its generic bimatoprost product in 2016, but Allergan was not yet done. In 2017—seven years after the generic company filed its ANDA—Allergan filed a fourth case on yet another patent in a different jurisdiction, seeking a jury trial and damages.[37] The asserted patent was once again related to one that Allergan had previously litigated, and was filed after Allergan's losses in the three prior litigations. The fourth case, *Latisse IV*, resulted in a jury verdict and damages award of $39,000,000 for Allergan in 2023, which is currently on appeal.[38]



C. MIRABEGRON

Astellas has asserted five waves of serial patent litigation over eight years relating to its drug Myrbetriq (mirabegron), starting in 2016 when Astellas sued nine generic companies seeking approval for generic versions.[39] Myrbetriq is a product FDA-approved to treat overactive bladder, a condition impacting millions of people in the United States. In this initial case, *Myrbetriq I*, Astellas triggered the 30-month stay on the generic products' approval, asserting a compound patent and multiple secondary patents, all of which expired as of 2024.[40] Shortly before trial, and after defendants had expended significant resources litigating for approximately four years, Astellas entered into patent settlements with all generic filers providing for generic launch as of a specific date.[41]

[35] Order and Judgment, *Duke University v. Sandoz, Inc.*, No. 1:14-cv-01034-CCE-LPA (M.D.N.C. Aug. 31, 2015), ECF No. 71.
[36] *See Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955 (Fed. Cir. 2017).
[37] Complaint at ¶¶ 33-37, *Duke University v. Sandoz Inc.*, No. 2:17-cv-528-JRG, (E.D. Tex. July 7, 2017), ECF No. 1.
[38] *See* Appellant's Principal Br., *Duke University v. Sandoz Inc.*, No. 2024-1078 (Fed. Cir. Jan. 16, 2024), ECF No. 10.
[39] *See* Complaint, *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 1:16-cv-00905 (D. Del. Oct. 6, 2016), ECF No. 1.
[40] *Id.*
[41] Report and Recommendations at 6, *Astellas Pharma Inc. v. Lupin Ltd.*, No. 1:23-cv-00819 (D. Del. Apr. 19, 2024), ECF No. 200.

A few months after *Myrbetriq I* was dismissed, however, Astellas again sued all nine generic companies on the same product, this time asserting infringement of a new formulation patent that would not expire until 2030.[42] Six of the generic companies settled, several of which agreed to a launch date later than what they originally agreed to in their *Myrbetriq I* settlements.[43] The three remaining defendants proceeded to trial in June 2023 (three years after settling *Myrbetriq*), and prevailed.[44] On appeal, the Federal Circuit vacated and remanded.[45]

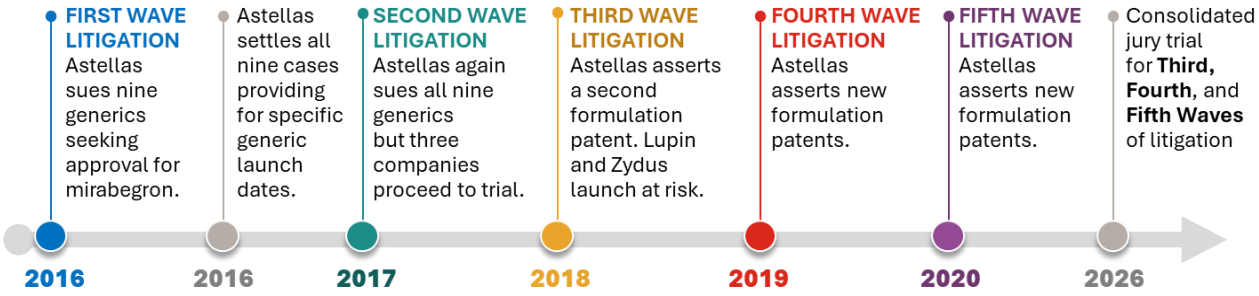
Shortly after the defendants' trial victory in *Myrbetriq II*, Astellas filed for and obtained yet another formulation patent, which it asserted against the defendants who had prevailed in *Myrbetriq II*.[46] In this third litigation, *Myrbetriq III*, *Astellas* attempted to use this new patent to preliminarily enjoin the generic companies from launching, but the injunction was denied and two generic filers launched at risk in April 2024.[47] Yet Astellas' fight was not over. Astellas sought yet another bite at the apple—and another—continuing its pattern of serial patent litigation and asserting new formulation patents in a fourth and then fifth lawsuit.[48] A consolidated jury trial is set for February 2026 for the patents in the third, fourth and fifth waves of litigation.[49]

The impact of this serial patent litigation is significant. Seven of the nine original ANDA filers who engaged in the initial Hatch-Waxman litigation that terminated in a patent settlement with a negotiated entry date, did not launch at that date, and still have not launched. Given the second wave of litigation, seven of the generic filers entered into a *second* patent settlement providing for an even later generic entry date than what was agreed in the first settlement, presumably to avoid the costs and uncertainty associated with continued and open-ended litigation.

The two generic companies that did not take the second settlement, and that instead took on the added costs and risk of litigating and launching their products, now face the threat of significant lost profits damages, in addition to an open-ended period of litigation cost, risk, and

[42] Complaint, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 1:20-cv-1589 (D. Del. Nov. 24, 2020), ECF No. 1.
[43] *See* Stipulations of Dismissal, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 1:20-cv-1589 (D. Del.), ECF Nos. 203, 419, 455, 465, 470, 520.
[44] Memorandum and Order, *Astellas Pharma Inc. v. Sandoz Inc.*, No. 1:20-cv-1589 D. Del. (June 9, 2023) ECF No. 571.
[45] *Astellas Pharma Inc. v. Sandoz Inc.*, 117 F.4th 1371 (Fed. Cir. 2024).
[46] Complaint, *Astellas Pharma Inc. v. Lupin Ltd*., No. 1-23-cv-00819 (D. Del. Jul. 28, 2023), ECF No. 1.
[47] The other defendants agreed to settle.
[48] See fourth-wave litigations filed on March 22, 2024 as Civil Action Nos. 24-939 and 24-940, and fifth-wave litigations filed in the District of Delaware on September 24, 2024 as Civil Action Nos. 24-1069 (D. Del.) and 24-1084.
[49] Supplemental Scheduling Order, *Astellas Pharma Inc. v. Lupin Ltd*, No. 1:23-cv-00819 (D. Del. Jan. 29, 2025), ECF No. 426.

uncertainty.[50] A conservative calculation[51] suggests that the healthcare system would have spent an additional $51 million per year for monopoly-priced Myrbetriq® had the two generic manufacturers opted not to launch at risk and take on the added burdens of continued serial patent litigation. Given how the ongoing litigations for the two generic launchers have proceeded, however, generic companies may think twice about how many products to invest in, and whether to launch at the earliest opportunity after resolution of the Hatch-Waxman case, given the potential for unpredictable, yearslong serial patent litigation.



D. PIRFENIDONE — Genentech

Genentech engaged in serial patent litigation over its product Esbriet (pirfenidone) over six years. The FDA approved pirfenidone in October 2014 for the treatment of idiopathic pulmonary fibrosis ("IPF"), a chronic and irreversible lung disease affecting more than 250,000 people in the United States.[52]In its initial infringement suit, *Esbriet* I, Genentech asserted twenty patents against twenty-eight generic companies who were seeking to commercialize generic pirfenidone products in 2019, triggering a 30-month stay on their FDA approval until June 2022.[53] The pirfenidone compound was discovered by another company in the 1970s,[54] so its 20-year term of patent protection had expired long before the litigation began. As such, the branded manufacturer asserted 20 non-compound patents.

All but one of the generic companies settled before trial for a date-certain launch. The only defendant who did not settle obtained a successful judgment from the trial court declaring all asserted patents invalid and/or not infringed.[55] This was affirmed by the Federal Circuit in

[50] Despite having already asserted four formulation patents, the brand is seeking additional formulation patents. See, for example, continuation application 19/053,451 (filed February 24, 2025), which if issued, would be the fifth formulation patent procured by the brand.

[51] This calculation assumes that the two generics do not gain additional market share beyond current levels (i.e., they maintain their market share as of Q3 2024) and that they do not lower their price from what's offered in Q3 2024.

[52] Pulmonary Fibrosis Foundation, https://www.pulmonaryfibrosis.org/understanding-pff/about-pulmonary-fibrosis/what-is-pulmonary-fibrosis.

[53] Complaint, *Genentech, Inc. v. Laurus Labs, Ltd.*, No. 1:19-cv-00078 (D. Del. Jan. 14, 2019), ECF No. 1.

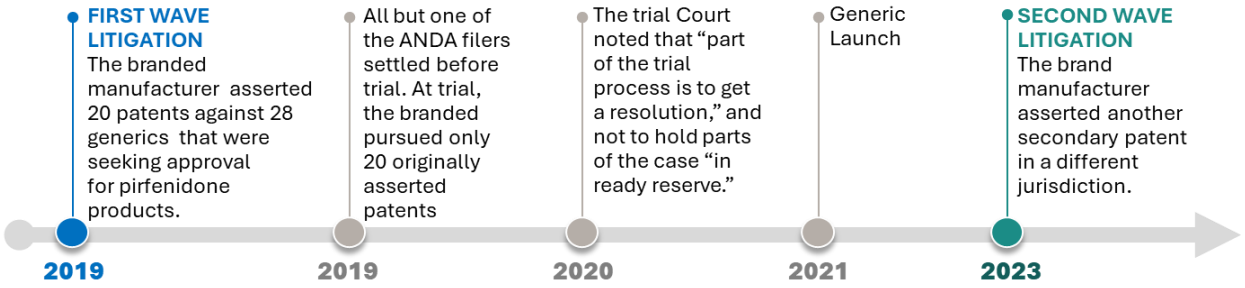
[54] *Genentech, Inc. v. Sandoz, Inc.*, 55 F.4th 1368, 1371 (Fed. Cir. 2022).

[55] *Genentech, Inc. v. Sandoz, Inc.,* 592 F.Supp.3d 355 (D. Del. 2022).

2022.[56] The generic challenger successfully cleared all asserted patents and defeated requests for emergency injunctive relief filed at the district court and appellate court, paving the way for it to launch its product as contemplated by the Hatch-Waxman Act.

At trial in *Esbriet I*, Genentech pursued only a subset of the 20 originally asserted patents, telling the Court that it would be "far fetched" that the dropped patents and claims would be reasserted in the future.[57] This prompted the judge to observe that "part of the trial process is to get a resolution," and not to hold parts of the case "in ready reserve."[58] But that is exactly what Genentech did.

In 2023, following the generic launch, Genentech asserted another secondary patent in a different jurisdiction, despite having obtained that patent before the first suit was filed in 2019.[59] This second lawsuit, *Esbriet II*, was filed more than a year after the generic challenger's launch and nearly five years after the ANDA filing.[60] In that case, Genentech now claims that the generic manufacturer should be responsible for all of its lost profits,[61] including from sales lost to other generic filers who launched pursuant to the terms of their settlement agreements. *Esbriet II* is still pending and no trial date has been set.[62]



E. TASIMELTEON

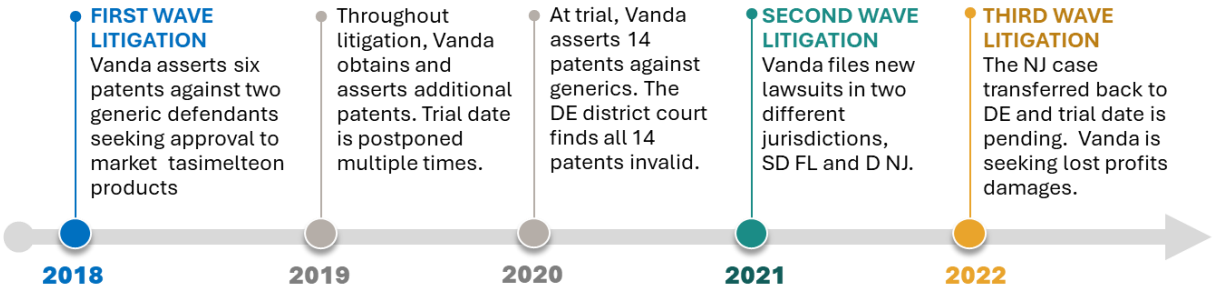
Vanda's Hetlioz (tasimelteon) product has been the subject of three waves of serial patent litigation over six years. Vanda first sued two generic defendants in 2018 in the District of Delaware over their ANDAs seeking approval to market generic tasimelteon products, thereby triggering the 30-month stay on their approval.[63] Tasimelteon is FDA-approved to treat a chronic circadian rhythm disorder that occurs in up to 70% of totally blind individuals. Vanda's original

[56] *Genentech, Inc. v. Sandoz Inc.*, 55 F.4th 1368 (Fed. Cir. 2022)
[57] Joint Status Report Ex. C at 35, *Genentech, Inc. v. Sandoz Inc.*, No. 1:19-cv-00078 (D. Del. Mar. 29, 2022) ECF No. 387-1.
[58] *Id.* at 37.
[59] Complaint, *Genentech, Inc. v. Sandoz, Inc.*, No. 23-cv-04085 (D.N.J. Jul. 31, 2023), ECF No. 1.
[60] *Id.* at ¶¶ 17, 20.
[61] *Id.*
[62] Pretrial Scheduling Order, *Genentech, Inc. v. Sandoz, Inc.*, No. 23-cv-04085 (D.N.J. Jun 6, 2024), ECF No. 69.
[63] *See* Complaint, *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 1:18-cv-00651 (D. Del. Apr. 30, 2018), ECF No. 1.

complaint asserted six patents.[64] Throughout the litigation, Vanda repeatedly obtained and asserted additional patents, resulting in the trial date being postponed multiple times. Ultimately, Vanda ended up asserting fourteen patents, which resulted in the district court finally telling Vanda that "they should not plan on ever getting to litigate in another case patents associated with these products."[65] Vanda agreed. After trial, at the end of 2022, the district court found all of Vanda's asserted patents invalid, and the Federal Circuit affirmed.[66]

Meanwhile, despite Vanda's representations that it would not assert additional patents, and in a blatant attempt to avoid the court in which it agreed not to litigate additional patents, Vanda proceeded to file two new lawsuits in two different jurisdictions, the Southern District of Florida and the District of New Jersey.[67] The patent that Vanda asserted in the new cases was related to the patents that were found invalid in the first case. The Florida case was dismissed. The New Jersey case was transferred back to Delaware and remains pending. In that case, Vanda is seeking lost profits damages from the generic companies' launches following their original trial victory.

Vanda continues to obtain and list new patents in the Orange Book. There are currently over 30 patents listed for tasimelteon, many of which have yet to be asserted.[68] The vast majority of the recently-listed patents are related to patents that have already been asserted (and on which the generic defendants prevailed).



[64] *See id.*

[65] Answer to First Am. Compl. and Counterclaims, *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 1:23-cv-00152, (D. Del. May 26, 2023), ECF No. 96; *see also Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, 2023 WL 1883357, at *1 n.2 (D. N.J. Feb. 10, 2023) ("Defendants assert that Vanda 'expressly committed to the district court in Delaware that, in exchange for securing a later trial date and adding other later-issued patents to the Delaware litigation, Vanda would not assert any additional patents against Teva's and Apotex's tasimelteon products.'").

[66] *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, 2023 WL 3335538, at *1 (Fed. Cir. May 10, 2023), *cert. denied*, 144 S. Ct. 1393 (2024).

[67] Complaint, *Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 24-cv-1345 (D. Del. Dec. 9, 2024), ECF No. 1; Complaint, *Vanda Pharms., Inc. v. Apotex Inc.*, No. 24-cv-1344 (D. Del. Dec. 9, 2024), ECF No. 1.

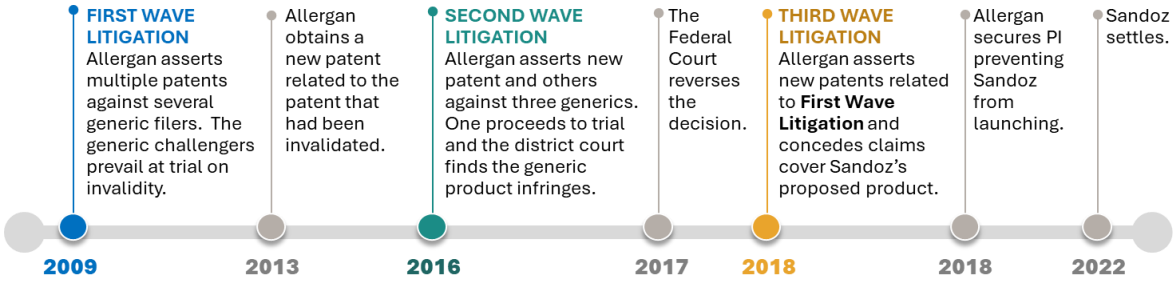
[68] Patent and Exclusivity for: N205677, Tasimelteon (Hetlioz) Capsule 20MG, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205677&Appl_type=N.

F. BRIMONIDINE / TIMOLOL

Allergan engaged in serial patent litigation over its combination product brimonidine/timolol, Combigan. In October 2007, the FDA approved brimonidine ophthalmic solution for the treatment of glaucoma and ocular hypertension. Allergan's serial patent litigation involved at least three separate waves of litigation over thirteen years. In the first wave in 2009, *Combigan I*, Allergan asserted multiple patents against several generic filers.[69] After an adverse district court judgment, the generic challengers prevailed on appeal regarding the obviousness of one of the asserted patents.[70] After the Federal Circuit's decision, Allergan obtained a new, related patent to the patent that had been invalidated.

Allergan asserted this new patent, along with others, in the second wave of litigation in April 2012, *Combigan II*. After Allergan initiated *Combigan II*, two of the generic challengers settled, but a third proceeded to trial. In 2016 the district court found that the generic product infringed one of the asserted patents. This was reversed by the Federal Circuit in April 2017.[71]

Six months later, in October 2017, Allergan then pursued yet another wave of litigation against the prevailing generic company in *Combigan II*, asserting newly-issued patents that related to the previously-invalidated patent from *Combigan I*. Allergan conceded in its complaint that these new third-wave patents were obtained specifically to ensure that the claims covered the generic company's proposed product.[72] In 2018, Allergan was able to secure a preliminary injunction preventing the generic filer from launching its generic product.[73] The generic filer ultimately settled in 2022. [74]



G. CABOZANTINIB

A generic company has already endured multiple waves of litigation, including two trials, related to Orange Book listed patents related to cabozantinib, the active ingredient in Cabometyx.

[69] *See, e.g.*, Complaint, *Allergan, Inc. v. Sandoz Inc.*, 2:09-cv-00097 (E.D. Tex. Apr. 7, 2009), ECF No. 1.
[70] *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1293 (Fed. Cir. 2013).
[71] *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 996 (Fed. Cir. 2017).
[72] Amended Complaint at ¶ 32, *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129 (D.N.J. Apr. 6, 2018), ECF No. 66.
[73] Order, *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129 (D.N.J. July 13, 2018), ECF 155.
[74] Stipulation and Order, *Allergan Sales LLC v. Sandoz, Inc.*, No. 2:17-cv-10129 (D.N.J. Jan. 28, 2022), ECF No. 310.

Cabometyx is a blockbuster cancer drug owned by Exelixis. In 2019, Exelixis sued the generic company for patent infringement related to certain Orange Book listed patents, including a patent covering a particular polymorphic form of cabozantinib, thereby triggering the 30-month stay of FDA approval.[75] In this litigation, *Cabometyx I*, the generic challenger argued that its ANDA product contained a different polymorphic form and therefore did not infringe.

While the original case was pending, Exelixis sought broader continuation claims that were not limited to a particular polymorphic form, but instead, covered any "crystalline malate salt" of cabozantinib.[76] In February 2022, Exelixis filed a complaint asserting these new broader patents, *Cabometyx II*.[77] To avoid serial trials, the generic company sought to have the various asserted patents tried in a single trial.[78] The court, however, decided to proceed with the first trial on only the originally asserted patents in *Cabometyx I*.[79] Trial on the original patents was held in May 2022. Following that trial, the Court held that the proposed ANDA product did not infringe the asserted polymorph patent.[80]

In the meantime, Exelixis also obtained a formulation patent. In July 2022, shortly after finishing the original trial, Exelixis sued the generic company again on its new formulation patent in *Cabometyx III*.[81] That case was consolidated with the *Cabometyx II* litigation and proceeded to a second trial in October 2023. Following trial, the Court found: (1) that the salt patents from *Cabometyx II* were infringed and not invalid; and (2) that the proposed ANDA product did not infringe the formulation patent from *Cabometyx III*.[82] That decision is currently on appeal.[83]

After the conclusion of the second trial, Exelixis obtained a narrower continuation of the formulation patent that does not claim a glidant.[84] That patent is now listed in the Orange Book[85] and was recently asserted against the generic challenger in another wave of serial patent litigation.[86] The generic company has experienced two waves of litigation so far. During both waves it has obtained a judgment of noninfringement on certain patents. Rather than clearing a path to market, however, the generic's victories have simply led to additional related patents being asserted against it and additional costly litigation.

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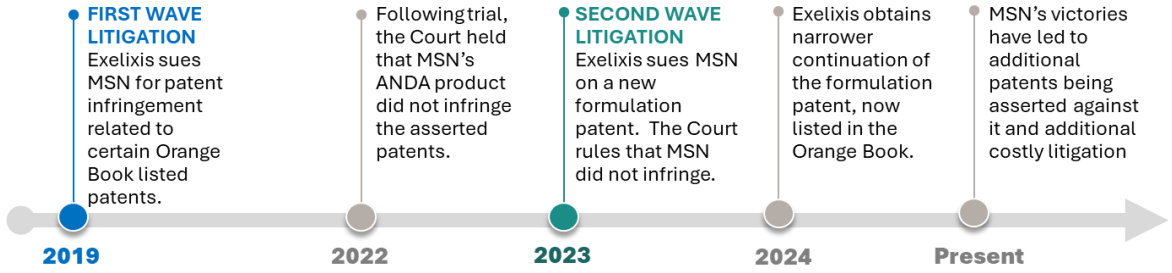
[75] Complaint, *Exelixis Inc. v. MSN Labs. Private Ltd.*, No. 1:19-cv-2017 (D. Del. Oct. 29, 2019), ECF No. 1.
[76] U.S. Patent Nos. 11,091,439, 11,091,440 and 11,098,015.
[77] Complaint, *Exelixis Inc. v. MSN Labs. Private Ltd.*, No. 1:22-cv-0228 (D. Del. Feb. 23, 2022), ECF No. 1.
[78] Transcript of March 18, 2022 Status Conference at 3, *Id.*, ECF No. 18.
[79] *Id.* at 26 (reasoning that "the only thing that will actually result, in my opinion, of ever having a second trial is if [the Form N-2 patent is] found to be not infringed and not obvious, then there's something to try at a second case"). That is precisely the scenario that occurred.
[80] *Exelixis Inc. v. MSN Labs. Private Ltd.*, 2024 WL 4491176 at *9-10 (D. Del. Oct. 15, 2024).
[81] Complaint, *Exelixis Inc. v. MSN Labs. Private Ltd.*, No. 1:22-cv-00945 (D. Del. Jul. 18, 2022), ECF No. 1.
[82] *Exelixis Inc. v. MSN Labs. Private Ltd.*, 2024 WL 4491176 at *34 (D. Del. Oct. 15, 2024).
[83] *Exelixis Inc. v. MSN Labs. Private Ltd.*, Nos. 2025-1236, -1241 (Fed. Cir.)
[84] U.S. Patent No. 12,128,039 (issued October 29, 2024).
[85] Patent and Exclusivity for Cabozantinib S-Malate (Cabometyx) Tablet EQ 20mg Base, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208692&Appl_type=N.
[86] Complaint, *Exelixis Inc. v. MSN Labs. Private Ltd.*, No. 1:25-cv-00346 (D. Del. Mar. 19, 2025), ECF No. 1.



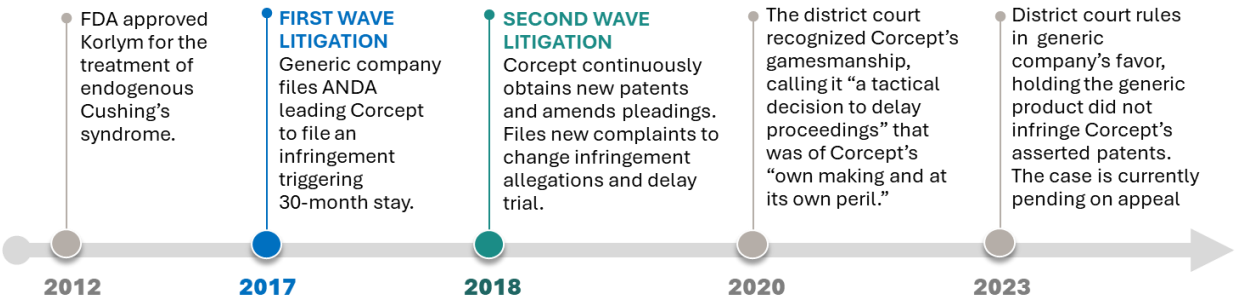
H. MIFEPRISTONE

Over seven years, Corcept engaged in serial patent litigation against a generic company in attempt to maintain a monopoly over its only product, Korlym (mifepristone). In 2012, the FDA approved Korlym for the treatment of endogenous Cushing's syndrome, a rare disease affecting approximately 20,000 patients in the United States that can be fatal if left untreated. Years later, in December 2017, a generic company filed an ANDA seeking FDA approval to market a more affordable generic version of Korlym, leading Corcept to file an infringement action to trigger the 30-month stay of FDA approval.[87] This initial infringement action, however, was just the beginning on Corcept's litigation tactics.

From its initial complaint in March 2018 until the parties ultimately reached trial in September 2023, Corcept repeatedly moved the goal posts in attempt to block generic competition and prolong litigation. During this time, Corcept continuously obtained new patents amended its pleadings, and filed new complaints to change the infringement allegations and delay trial.[88] In fact, shortly after the district court denied its motion for summary judgment of infringement, Corcept asserted two patents that it had been holding back for two years, even though it had filed suit against another generic company years prior.[89] The district court criticized Corcept's gamesmanship, calling it "a tactical decision to delay proceedings" that was of Corcept's "own making and at its own peril."[90] It further complained that "[t]his Court cannot function properly if all parties before it were permitted to litigate their claims in piecemeal fashion, as has happened here."[91] By the time the district court held trial, Corcept had asserted nine different patents and voluntarily dismissed seven of them. In December 2023, after years of litigation, the

[87] Complaint, *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 1:18-cv-03632 (D.N.J. March 15, 2018), ECF No. 1.
[88] *See, e.g.*, First Amended Complaint, *Id.*, (Jul. 6, 2018), ECF No. 15; Order, *Id.* (Feb. 27, 2023) ECF No. 229; Text Order, *Id.* (Apr. 24, 2023) ECF No. 239.
[89] *See* Complaint, *Corcept Therapeutics, Inc. v. Hikma Pharms. USA Inc.*, No. 2:21-cv-05034 (D.N.J. Mar. 12, 2021), ECF No. 1.
[90] Text Order, *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 1:18-cv-03632 (D.N.J. Apr. 24, 2023), ECF No 239.
[91] *Id.*

district court ruled in the generic company's favor, holding its generic product did not infringe either of the last two asserted Corcept patents.[92] The case is currently pending on appeal.



V. Additional Case Studies Concerning Biosimilars

While biosimilar litigation has not been around as long as Hatch-Waxman litigation, it too has already seen examples of serial patent litigation.

One example of serial patent litigation in the biosimilar context is Amgen's litigation against a biosimilar applicant related to pegfilgrastim/filgrastim. In 2015, Amgen asserted infringement against a biosimilar applicant concerning a patent reciting a method of refolding a protein.[93] Following trial, the district court held the biosimilar's processes for preparing its biosimilars did not infringe.[94] The Federal Circuit affirmed.[95] Shortly after the Federal Circuit affirmed the district court's finding of non-infringement, however, Amgen obtained a new, related patent and asserted infringement against the same biosimilar company's pegfilgrastim and filgrastim products again.[96] Amgen's follow-on litigation did not conclude until November 2019—two years after the Federal Circuit affirmed the biosimilar's non-infringement in the original litigation—when the case settled.[97]

Another example concerns Regeneron's Eylea (aflibercept) product. Regeneron filed its first patent infringement suit against a biosimilar applicant in August 2022, followed by several additional complaints against other applicants.[98] Nearly two years later, the district court granted several permanent injunctions in Regeneron's favor, holding the biosimilar applicants infringed asserted claims.[99] In the meantime, another company filed an application for an aflibercept

[92] Opinion, *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, No. 1:18-cv-03632 (D.N.J. Dec. 29, 2023), ECF No. 301.
[93] Complaint, *Amgen, Inc. v. Apotex Inc.*, No. 15-cv-61631 (S.D. Fla. Aug. 6, 2015).
[94] *Amgen, Inc. v. Apotex Inc.*, No. 15-61631, 2016 WL 11783299 (S.D. Fla. Sept. 6, 2016).
[95] *Amgen, Inc. v. Apotex Inc.*, 712 F. App'x 985 (Fed. Cir. Nov. 13, 2017).
[96] Complaint at ¶¶ 6, 25-28, *Amgen, Inc. v. Apotex Inc.*, No. 18-61828 (S.D. Fla. Aug. 7, 2018), ECF No. 1.
[97] Stipulation of Dismissal, *Amgen, Inc. v. Accord Biopharma*, No. 18-61828 (S.D. Fla. Nov. 14, 2019), ECF No. 119.
[98] *See, e.g.*, Complaint, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 1-22-cv-00061 (W.D. Va. Aug. 2, 2022), ECF No. 1.
[99] *See, e.g.*, Order, *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 1-22-cv-00061 (W.D. Va. June 1, 2024), ECF Nos. 794, 795.

biosimilar, triggering a new complaint in January 2024.[100] This time, however, the district court held Regeneron was not likely to succeed in proving infringement and denied its motion for injunctive relief.[101] This decision was affirmed on appeal, with the Federal Circuit emphasizing the "undisputed fact that [the biosimilar] product does not contain a buffer separate from the VEGF antagonist," as required by the asserted claims.[102] Following the district court's ruling, the biosimilar company launched its product while Regeneron sought additional patent protection in attempt to capture the biosimilar's product. In particular, Regeneron filed a new continuation patent application that this time did not require a buffer—the element that formed the biosimilar product's non-infringement defense. A new patent issued in June 2025, and on the same day, Regeneron filed a new complaint against the same biosimilar company in a different district.[103]

These case examples, like the Hatch-Waxman case examples above, illustrate how brand pharmaceutical companies can weaponize serial patent litigation to repeatedly seek another bite at the apple.

VI. Potential Legislative Solutions

A key means of curbing the issue of serial patent litigation is through legislative reform. Policymakers should consider strategies for curbing serial patent litigation in order to thwart improper attempts to delay competition and restore the balance intended by the Hatch-Waxman Act. Specifically, branded manufacturers should be incentivized to obtain and assert their strongest claims in a timely manner and get penalized for withholding, delaying issuance, or stockpiling patents with the aim of delaying or deterring generic competition. For example, Congress should consider amending the Hatch-Waxman Act to limit the remedies available for patents that are obtained after a generic's ANDA has been submitted. Congress should also limit the circumstances when branded manufacturers can file serial patent litigations.

VII. Conclusion

Serial patent litigation allows brand pharmaceutical companies to undermine one of Congress' key goals of speeding the introduction of low-cost generic drugs to market. Legislative solutions are urgently needed to address the substantial harm that has impacted—and will continue to impact—both generic pharmaceutical companies and American patients.

[100] *See* Complaint, *Regeneron Pharms., Inc. v. Amgen, Inc.*, No. 1:24-cv-00039 (N.D. Va. Jan. 10, 2024), ECF No. 1.
[101] Order, *Regeneron Pharms., Inc. v. Amgen, Inc.*, No. 1:24-cv-00039 (N.D. Va. Sept. 23, 2024), ECF No. 257; *see also Regeneron Pharms, Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372 (Fed. Cir. 2025).
[102] *Regeneron Pharms., Inc. v. Amgen Inc.*, 130 F.4th 1372, 1384 (Fed. Cir. 2025).
[103] *See* Complaint, *Regeneron Pharms., Inc. v. Amgen, Inc.*, No. 2-25-cv-05499 (C.D. Cal. Jun. 17, 2025), ECF No. 1.