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before the

U.S. House Subcommittee on Courts, Intellectual Property,
Artificial Intelligence, and the Internet

for the hearing on

"**Medicines and IP: Balancing Innovation and Access**"

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Generation Patient was created and is led by young adults living with chronic and rare health conditions. We are one of the few patient groups that has declined all private industry funding, including from brand drug companies, generic drug manufacturers, and insurance companies, to retain the integrity of our policy priorities. Our community depends on medications that can cost tens or hundreds of thousands of dollars a year and the patent system directly shapes whether those treatments are affordable to the millions of young adults across America who need them.

Drug patent policy must strike a balance between incentivizing genuine biomedical innovation and enabling competition after limited exclusive rights expire. Achieving this balance is crucial for ensuring affordable access to medicines for young adults with chronic conditions, many of whom rely on high-cost therapeutics. However, brand companies typically exploit gaps in the patent system to disrupt that balance and delay generic competition long beyond the expiration of foundational exclusive rights. One of the primary mechanisms that drug companies use to delay competition is filing patent applications claiming inventions that are patentably indistinct from earlier patents filed by the same applicant. When these overlapping patent applications are detected, examiners at the U.S. Patent and Trademark Office (USPTO) reject the later claims under double patenting grounds because they are too similar to one or more earlier patents.

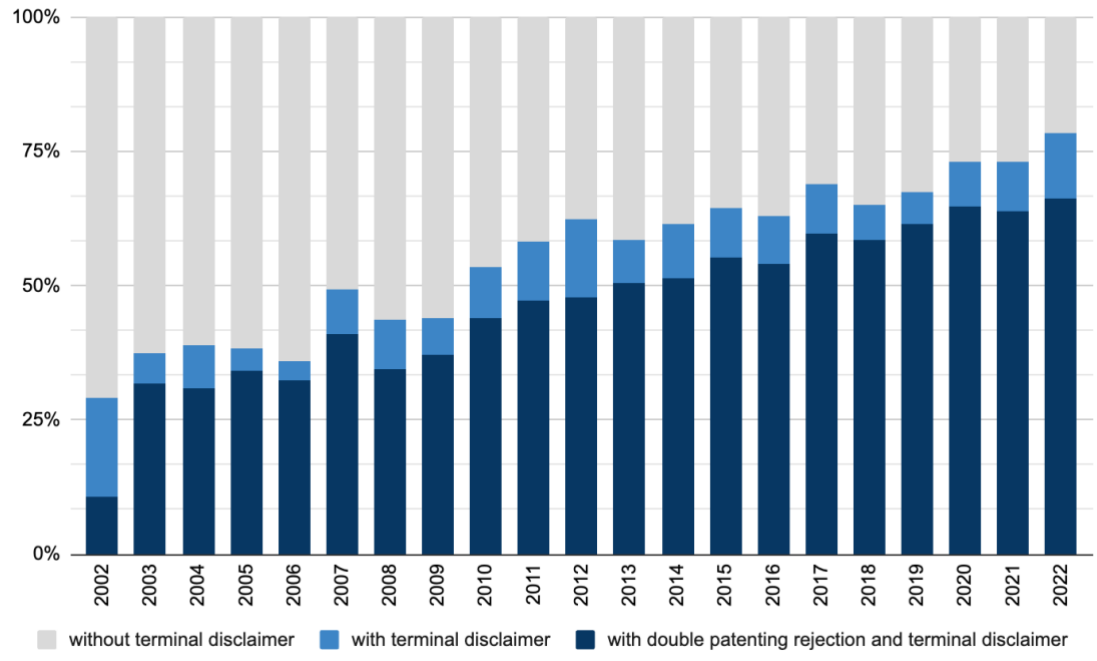
Applicants can overcome these rejections by agreeing to shorten the term of the later-filed patent so that it expires on the same date as the earlier patent. These agreements are formalized through *terminal disclaimers.* When a terminal disclaimer is entered, the USPTO withdraws the double patenting rejection, and the patent is cleared for issuance if other office actions have been resolved. With terminal disclaimers, the applicant does not extend the length of exclusive protection but does increase the number of patents that can be asserted against competitors.

1. Terminal disclaimers have increased over time and are now routinely made on drug patents

Research by Sean Tu, Aaron Kesselheim, and Bernard Chao found that 45 percent of small-molecule drug patents filed between 2002 and 2023 had obviousness-type double patenting rejections resolved through terminal disclaimers.[1] Their study combined openly available data with commercial legal analytics platforms. Relying on open data sources, Generation Patient independently replicated these findings. Our analysis of 7,836 drug patents filed from 2002 to 2022 and listed in any edition of the Orange Book shows that 50 percent had both a double patenting rejection in their prosecution history and a terminal disclaimer approved by the USPTO.

Expanding to all 2002-2022 patents in the Orange Book regardless of whether the prosecution history clearly shows that the USPTO issued a double patenting rejection, we found that 59 percent have terminal disclaimers. In the Orange Book edition available as of March 2026, which includes 6,247 patents listed, the share with a confirmed terminal disclaimer is 59.4 percent.

Graph 1. Share of Orange Book patents with terminal disclaimers, by patent filing year



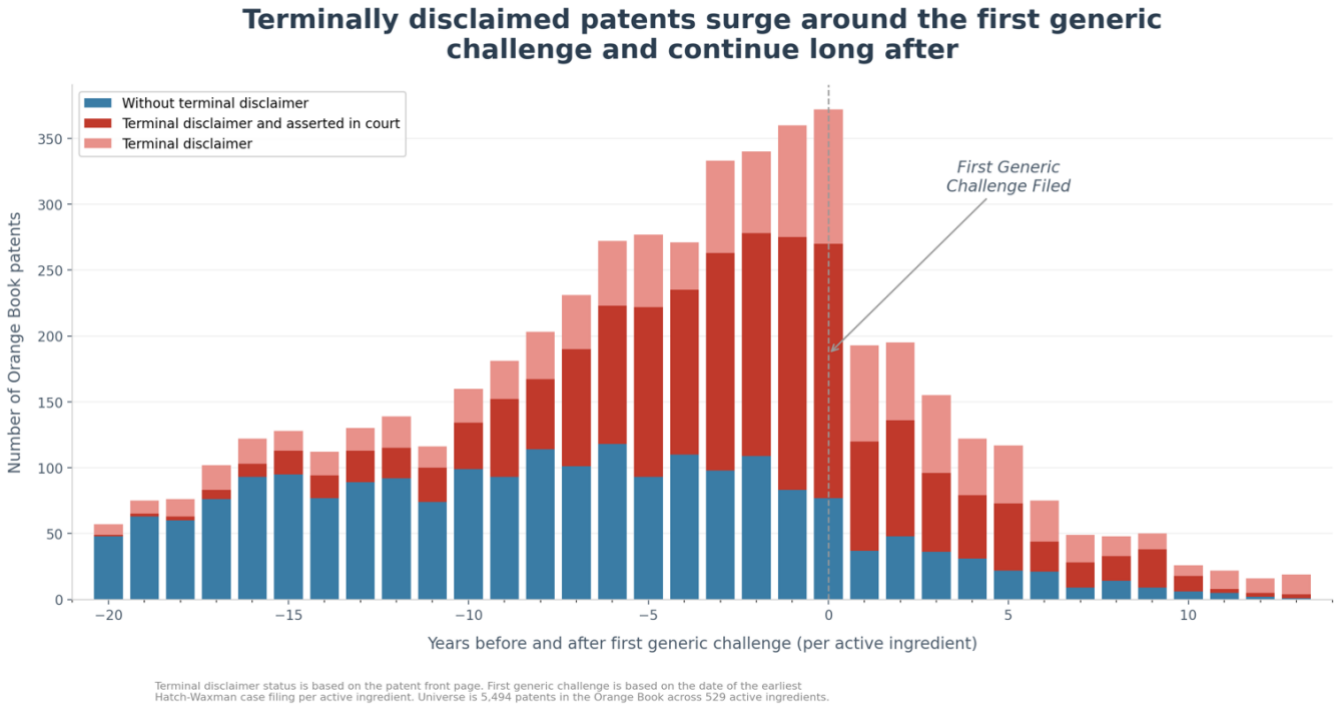
Drug companies have steadily increased double patenting and terminal disclaimer practices over the past two decades. Roughly 36 percent of the drug patents in our analysis with a 2002-2006 filing date had an approved terminal disclaimer. By 2012-2016, the share of drug patents with

[1] S. Sean Tu, Aaron S. Kesselheim & Bernard Chao, Extent of Drug Patents With Terminal Disclaimers and Obviousness-Type Double Patenting Rejections, JAMA (2024).

terminal disclaimers climbed to 62 percent and then rose again to nearly 70 percent among those with 2017-2021 filing dates. The rise in terminal disclaimers coincides with the well-documented growth of patent continuations,[2] a practice that increases the likelihood that the USPTO will find the resulting claims substantially indistinguishable from earlier filings by the same applicant.

2. Drug companies create patent thickets to increase litigation costs and deter competition

Research by Generation Patient shows that drug companies ramp up patent filings as generic competition approaches. Generation Patient reviewed the Orange Book patent listings for 529 active ingredients with at least one Paragraph IV Abbreviated New Drug Application (ANDA) filed from 2010 to 2025. Our analysis shows that a third of Orange Book patents filed a decade before the first generic challenge have a terminal disclaimer. In the years immediately surrounding and following the first challenge, the share of Orange Book patents that have terminal disclaimers increases sharply. More than 80 percent of patents filed after the first generic challenge carry a terminal disclaimer. Drug companies probably secure these patents to increase litigation costs and discourage generic challenges. The large share of disclaimers after the first ANDA challenge also suggests that drug companies adjust their thickets in response to how the first case unfolds.



Young adults with chronic and rare conditions rely on innovation and strong incentives to promote meaningful research and development. However, thickets of late-stage patents with terminal disclaimers reflect something entirely different. Brand drug companies file overlapping

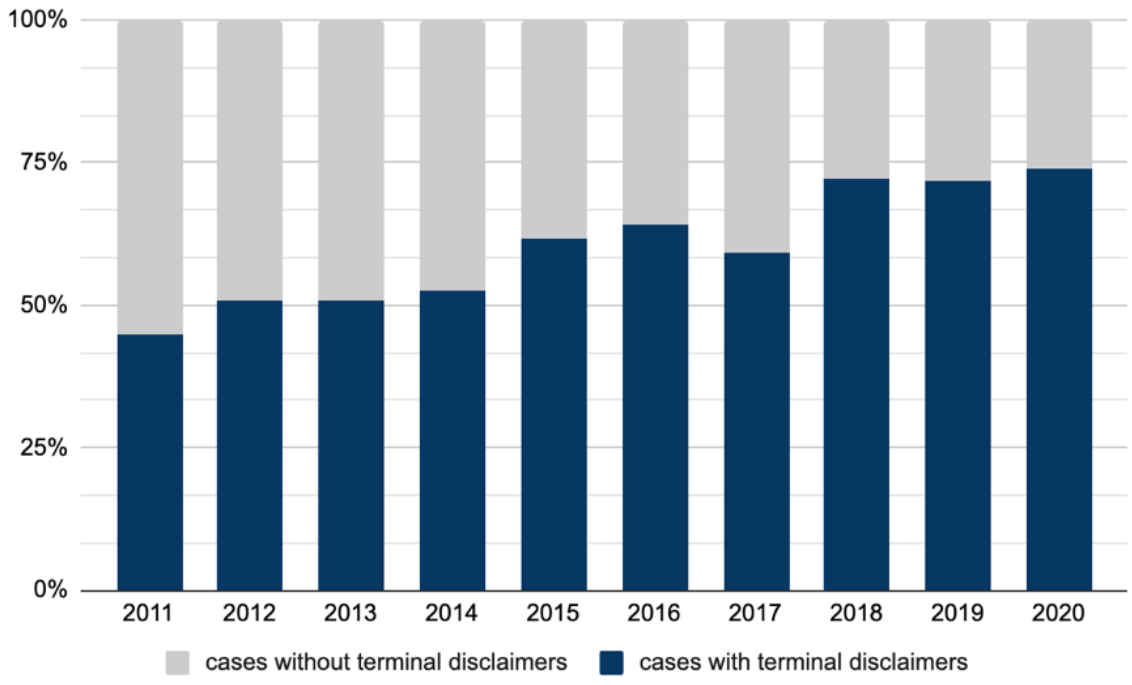
[2] Michael Carrier & S. Sean Tu, Why Pharmaceutical Patent Thickets Are Unique, 32 Tex. Intell. Prop. L.J. 79 (2023)

applications to expand their patent arsenal and deter competition. Each of these patents can be asserted independently against prospective competitors, deterring some generic manufacturers from challenging the thicket altogether and forcing others to endure years of costly litigation before they can enter the market. Young adult patients who are balancing finances, education, and employment while living with a chronic condition face the impossible reality of paying high prices for medications they need or risking serious health consequences by going without them.

3. Drug companies routinely assert patents with terminal disclaimers to delay competition

Generation Patient has also analyzed data compiled by the USPTO Office of the Chief Economist to study how often drug companies assert terminally disclaimed patents in district courts. We reviewed 3,214 distinct district court dockets between 2003 and 2020 involving 1,914 unique patents in our compilation of historical Orange Book editions with a 2002-2022 filing date. Across those 1,914 litigated patents, 50 percent have a confirmed double patenting rejection in their prosecution history and terminal disclaimer approved by the USPTO. Expanding to all the litigated Orange Book patents regardless of whether the prosecution history clearly confirms a double patenting rejection from the USPTO, our study shows that 62 percent have terminal disclaimers.

Graph 2. Share of district court cases involving at least one Orange Book patent with terminal disclaimer, by case filing year



District court litigation data shows that drug companies are increasingly asserting patents with terminal disclaimers. Graph 2 explores what share of district court drug litigation between 2011 and 2020 involved at least one patent with terminal disclaimer. Approximately 74 percent of all drug patent cases filed in 2020 involved at least one patent with terminal disclaimer, up from 45 percent a decade earlier. Across this period, 60 percent of all drug disputes involved at least one patent with terminal disclaimer. This indicates that the growing number of terminally disclaimed drug patents has also translated into more infringement assertions. To prevail, defendants in drug patent lawsuits must offer evidence of noninfringement or invalidity for every claim asserted against them. Each extra patent requires defendants to allocate additional resources to navigate the infringement allegations. Therefore, the growing assertion of terminally disclaimed patents increases litigation complexity, time, uncertainty, and costs. These added costs and risks discourage generic entry, prolonging the period during which patients face higher drug prices.

4. Patent thickets covering Xifaxan have delayed the entrance of cheaper generic competition

Rifaximin illustrates the mechanics of patent thickets in practice and how they delay affordable access for young adult patients. Rifaximin (Xifaxan) was discovered by Italian scientists over four decades ago and licensed to Salix Pharmaceuticals in 1996.[3] The Food and Drug Administration (FDA) has approved rifaximin for various indications since 2004, including the treatment of irritable bowel syndrome (IBS) with diarrhea in 2015. The earliest Orange Book patent associated with rifaximin expired in 2019. However, Salix built a thicket with more than 34 patents, 25 with terminal disclaimers, to assert against prospective competitors seeking to enter the U.S. market.

> "I think for me the biggest [challenge] was just the accessibility of [rifaximin]. I mean nothing beats what I was dealing with for five whole weeks trying to get it. That was actually the episode that landed me in the ER for dehydration, because I was having diarrhea upwards of at least 10 to 15 times a day. I couldn't work anymore during all of that. I had my own business. I ended up losing it, and in the state of New York, you can't apply for unemployment and get benefits if you're self-employed. So, we were trying to live a normal life, and it just was not going to happen under those conditions. So, accessibility was my key issue, as far as that goes. It did help with the symptoms. But I don't know what I would have done if I couldn't get it."
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> "Insurance said no. My pharmacy said, you can have it for $3,700, and I ended up ordering it from Canada, and paid $67 to have it delivered to my door, but I suffered for five more weeks with those in between. So, it really did help, and I don't know where I'd be without it."
>
> Patient. Source: https://www.cms.gov/files/document/xifaxan-pdf.pdf

[3] BioWorld, "Licensing agreement signed for rifaximin," BioWorld, Aug. 9, 1996

When Norwich filed an ANDA to market generic rifaximin in 2020, Salix asserted 26 patents, including 19 with terminal disclaimers.[4] Judge Richard Andrews presided over the case and, in 2022, issued an order invalidating four of the seven patents that reached trial, including two that claimed methods of treating IBS. In 2023, the USPTO granted Salix two new patents claiming methods of treating IBS *in females*. These patents were initially rejected under double patenting grounds and then issued after Salix made terminal disclaimers to resolve the office actions. Salix then asserted the newer patents claiming methods of treating IBS against Norwich in 2024.

American patients pay among the highest prices in the world for Xifaxan, largely because Salix has been able to assert their patent thickets to deter generic competition. With retail prices for sixty 550 mg tablets exceeding $2,500,[5] many Americans struggle to access Xifaxan and delay treatment during flare-ups.[6] Other American patients discontinue treatment due to high prices.[7] In 2025, the Medicare Drug Price Negotiation Program announced that it had negotiated a maximum price for Xifaxan of $1,000 for a 30-day supply. This negotiated price will be effective in 2027. By contrast, comparable quantities of rifaximin are available in Canada for approximately $240[8] and generic versions of this drug can be bought in countries like India for less than $100.[9]

5. Symbravo similarly illustrates how patent thickets increase uncertainty and litigation costs

Axsome Therapeutics has listed 94 patents in the Orange Book entry for Symbravo, a drug combination approved by the FDA in 2025 for treating migraines. Symbravo combines meloxicam and rizatriptan, two active ingredients first patented decades ago. Research by Generation Patient shows that 82 of the 94 patents listed in the Orange Book entry for Symbravo carry terminal disclaimers. Although most are interconnected through a complex terminal disclaimer linkage that traces back to a dosage form patent issued in 2017[10] and are therefore expected to expire in 2036 together with their earlier filed references, Axsome Therapeutics can assert each one of them individually against prospective generic manufacturers seeking to enter the market.

Court documents show that Axsome has already asserted 1,856 claims across 75 patents from their thicket against Apotex, a generic manufacturer seeking to enter the U.S. market.[11] That case was filed in September 2025 and is still ongoing as of May 2026. Apotex has sought to narrow

[4] Generation Patient, *Rifaximin Patents*, https://generationpatient.org/rifaximin-patents
[5] Xifaxan 2026 Prices, Coupons & Savings Tips, GoodRx, https://www.goodrx.com/xifaxan (last visited Apr. 22, 2026)
[6] Ctrs. for Medicare & Medicaid Servs., Transcript: Xifaxan Roundtable Event, Medicare Drug Price Negotiation Program Public Engagement Events (Apr. 28, 2025), https://www.cms.gov/files/document/xifaxan-pdf.pdf at 17
[7] *Id.* at 9 ("Most of the patients that I know, including myself, who were on Xifaxan were not able to stay on due to access issues and cost.")
[8] Xifaxan (Rifaximin), CanadaPharmacy.com, https://www.canadapharmacy.com/products/xifaxan (last visited Apr. 20, 2026)
[9] Jai Kumar, Brian Nohomovich & Leonid Shamban, *Why Does Rifaximin Cost 95 Percent More in the U.S. Than in Asia?*, KevinMD (May 28, 2025), https://kevinmd.com/2025/05/why-does-rifaximin-cost-95-percent-more-in-the-u-s-than-in-asia.html
[10] U.S. Patent No. 9,821,075
[11] *Axsome Therapeutics, Inc. v. Apotex Inc.*, No. 2:25-cv-16038 (D.N.J. filed Sept. 26, 2025).

the scope of this case, arguing that litigating 1,856 claims at once "will become a cost-prohibitive endeavor" instead of a "reasonable inquiry" into whether their ANDA infringes legitimate patent rights.[12] Apotex has argued that litigating all the asserted claims at once would subject them to a "Kafkaesque and cost-prohibitive nightmare requiring it to expend enormous amounts of money and resources to defend against what can only be described as a 'patent thicket.'"[13] Public records indicate that Apotex's motion to narrow the scope of this case is pending as of May 2026.

> "Young adult patients like me deserve a strong research and development system that encourages the type of meaningful biomedical breakthroughs that we desperately need. However, patent thickets serve an entirely different purpose. Patent thickets are about gaming the patent system to restrict generic and biosimilar competition and keeping drug prices high."
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> Peyton Miles. Source: https://generationpatient.org/s/peyton-miles-ethic-statement.pdf

Seventy of the 75 patents asserted by Axsome against Apotex are interlinked through disclaimers. Under the Eliminating Thickets to Increase Competition Act (ETHIC) (S. 2276; H.R. 3269), Axsome would have been able to assert no more than five patents against Apotex in this ANDA litigation.[14]

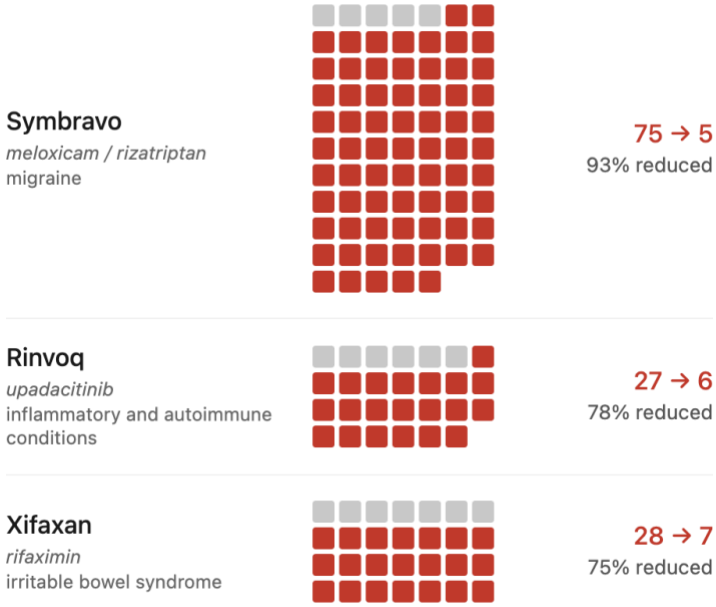
6. ETHIC is a targeted and balanced solution to increase competition and reduce drug prices

Congress must find bipartisan solutions to reduce high drug prices and healthcare costs. This will require solutions that strike a balance between incentivizing genuine biomedical innovation and enabling competition after limited exclusive rights expire. The ETHIC Act (S. 2276; H.R. 3269) offers a targeted solution to one of the primary types of patent gamesmanship that companies use to delay generic competition and impose high drug prices on American patients. Under the ETHIC Act, brand companies may assert no more than one patent per group interlinked through terminal disclaimers. Brand drug companies would still retain the prerogative to select which patent from their terminal disclaimer group they choose to assert. This is the type of solution that will promote competition while striking a balance between innovation incentives and access.

Applied to the Symbravo scenario, Axsome would have been able to assert no more than five patents against Apotex instead of 75. Applied to the rifaximin scenario, Salix would have been able to assert no more than seven patents against Norwich instead of 26. The ETHIC Act would also neutralize follow on infringement litigation involving patents from a terminally disclaimed group previously asserted in court against the same generic challenger. This provision of the ETHIC Act would have prevented the second lawsuit filed by Salix against Norwich in 2024, which alleges ANDA infringement based on a newer set of method-of-treatment claims from one of the terminally disclaimed patent families that was already invalidated in the 2020 case.

[12] Def.'s Opening Br. in Supp. of Its Rule 12(c) Mot. for Partial J. on the Pleadings at 1, Axsome Therapeutics, Inc. v. Apotex Inc., No. 2:25-cv-16038-MEF-AME (D.N.J. May 18, 2026), ECF No. 52.
[13] *Id.* at 17
[14] Generation Patient, *Symbravo Patents*, https://generationpatient.org/symbravo-patents

The bipartisan and bicameral ETHIC Act will curb anticompetitive patent thicket gamesmanship and reduce high drug prices for young American patients



Each box represents patents asserted in representative cases. Red boxes are patents that would be reduced by ETHIC. Reduced counts are based on terminal disclaimer linkages.

Data sources and methods

Patent universe. We compiled a dataset of drug patents that appeared in any edition of the Orange Book from inception until March 2026. Our compilation of Orange Book patents draws on monthly snapshots released between 2019 and 2026, supplemented by archived editions obtained from the National Bureau of Economic Research and a list secured through a public information request. This approach captures small-molecule drug patents that were listed in the Orange Book at any point during the study period, including those that have been delisted.

Terminal disclaimers. We reviewed all patents in our study and classified them as having a terminal disclaimer if the patent front page bears a terminal disclaimer notice. Patent front pages were extracted from the USPTO Patent Public Search database and Google Patents.

Litigation data. We used the USPTO Patent Litigation Docket Reports Data and the Stanford NPE Litigation Database to identify Hatch-Waxman court cases and infer the first ANDA filing dates.