



## The Issue

Branded drug and biologic manufacturers engage in anticompetitive behaviors to keep lower cost alternatives off the market. The abuse of tactics such as pay-for-delay patent settlements, product hopping, and citizen's petitions allow manufacturers to perpetuate significant profit by extending monopoly protections and preventing patient access to more affordable prescription drugs.

## The Evidence

### PAY-FOR-DELAY AND PATENT THICKETS

***Brand name drug and biologic companies engage in reverse payment patent settlements to delay competitors from introducing generic and biosimilar alternatives to the market.***

“Pay-for-delay” patent settlements use a variety of tactics to block competition and can be very difficult for the Federal Trade Commission (FTC) to prosecute. Even if fines and enforcement actions are taken by the FTC, the sales from extra weeks or months of monopoly power are highly profitable, which incentivizes brand manufacturers to pursue these settlement agreements. The FTC has noted that despite a large number of settlements, the number that are completed with explicit compensation between brand and generic manufacturers are low.<sup>1</sup> However, the number of settlements between brand-name and generic companies doubled between 2010 and 2017 and the majority have resulted in generic entry delay or restrictions.<sup>2</sup> It is likely that pay-for-delay deals have evolved to include other categories of value transfer that are less likely to attract antitrust scrutiny yet still effectively delay generic entry, such the transferring of patent rights not subject to litigation.<sup>3</sup>

“Pay-for-delay” is particularly prevalent in the biologics market, due in part to the complex patent thickets surrounding most blockbuster biologic products.<sup>4</sup> Patent thickets consist of patents for the active ingredient in addition to secondary patents on manufacturing processes, methods of use, delivery devices, and other aspects of a product. Because of the uncertainty and litigation cost for biosimilar manufacturers to challenge each patent, some opt to settle with the originator manufacturers instead. For example, in 2016 AbbVie secured an additional 6 years of patent exclusivity from settlements with biosimilar manufacturers for its blockbuster drug Humira.<sup>5</sup> As a result of these settlements, Humira biosimilars have only been launched on the US market since 2023, whereas they have been available in Europe since 2018 with discounts of nearly 80%.<sup>6</sup> It has been estimated that this delay resulted in \$2.2 billion in lost savings to Medicare.<sup>7</sup>

### PRODUCT HOPPING

***Before a brand product is susceptible to generic or biosimilar competition, manufacturers can extend its patent life and market exclusivity by making small adjustments to the product and then strategically move patients to this new, patent-protected version.***

In anticipation of generic competition, a brand manufacturer makes small, patent-protected changes to their original product that provide no significant clinical benefit—such as changing from a tablet to a capsule—but offer the manufacturer longer market exclusivity. They then work to direct consumers away from the original product formulation towards the new, patent-protected version. Manufacturer engagement in this tactic is costly, with one study showing that five recent product hops have cost the U.S. \$4.7 billion annually.<sup>8</sup>

For example, the drug manufacturer Reckitt Benckiser in 2009 “product hopped” Suboxone, a medication used to treat opioid use disorder, from a tablet formulation that was soon to be available as a generic to a sublingual film formulation that dissolves under the tongue. This orchestrated move involved raising the price of the tablets and then removing them from the market, preventing pharmacists from substituting the lower-priced generic tablets. Reckitt Benckiser switched most patients to the new, patent-protected formulation and generated \$1.9 billion in sales the year the generic formulation was available.<sup>9,10</sup>

Inhalers for asthma and chronic obstructive pulmonary disease (COPD) have been historically subject to “device hopping.” A study of patents and regulatory exclusivities for inhalers approved by the FDA from 1986 to 2020 found that out of 62 approved inhalers, 53 were brand-name products with a median protection period of 16 years.<sup>11</sup> Of these inhalers, only one included an ingredient with a new mechanism of action and more than half of the patents were for devices, rather than active ingredients. This extended the median exclusivity period to twenty-eight years for branded follow-on products. This underscores the need for reform, as our current regulatory system rewards incremental changes to existing products.

## CITIZEN PETITIONS

***The FDA is required to rule on petitions filed by interested parties, which are often competing pharmaceutical manufacturers, to block the approval of generics, biosimilars, or novel therapies based on safety concerns.***

The FDA implemented the citizen-petition process in the 1970s to allow citizens to voice concerns regarding safety or efficacy as a drug is being considered for approval. However, there is widespread, strategic misuse of the citizen-petition pathway by drug companies striving to hold off competition. Specifically, nearly half of the petitions filed by brand drug manufacturers that could have delayed generic entry from 2000 to 2012 were filed within a year and a half before the FDA approved a generic competitor, with roughly 40% filed a year or less before generic approval.<sup>12</sup>

For example, to maintain its monopoly, ViroPharma waged a campaign of citizen petition filings and lawsuits to delay the generic entry of its antibiotic Vancocin. Between 2006 and 2012, knowing that the FDA would not move forward with generic approval until all pending citizen petitions were resolved, ViroPharma submitted 43 petitions and filed 3 lawsuits against the FDA.<sup>13</sup> These citizen petitions claimed that competitors were not using adequate study designs to test their products. ViroPharma failed to provide any clinical data to support this argument and the petitions were rejected, but the company persisted with repeated citizen petitions of the same unsupported argument to delay generic entry.

Citizen petitions cost very little to file and pose no consequences for the filing party. Even in instances where citizen petition cases by pharmaceutical manufacturers are ultimately denied, each day of postponed competition could earn the company millions of dollars.

## The Solutions

### PAY-FOR-DELAY AND PATENT THICKETS

- *Preserve Access to Affordable Generics and Biosimilars Act.* In 2024, the Congressional Budget Office found the bill would reduce federal budget deficits by over \$1.65 billion over 10 years. The bill was reintroduced in the 119th Congress. This bipartisan bill would:
  - › Limit anticompetitive agreements that prevent or delay the introduction of lower cost generic or biosimilar products.
  - › Require that manufacturers prove an agreement is not anticompetitive rather than asking the FTC to prove an agreement is anticompetitive.
- Policy solutions that address both generics and biosimilars and attempt to contemplate newer generations of “pay-for-delay” settlements that may not involve direct payments. Alternatives to direct payments include (1) overvalued agreements where the generic firm delays entry but receives substantial compensation for assisting with the branded drug’s sale, and (2) “boy scout clauses,” which are agreements to conceal anticompetitive deal making.<sup>14</sup>

- *Eliminating Thickets to Increase Competition (ETHIC) Act*. This bipartisan bill would:
  - › Limit the number of patents that brand-name manufacturers can assert to one patent per family when suing for infringement.
- Direct the FDA to delist invalid patents from the Orange Book.
- Require manufacturers of brand biologics to disclose patent rights in their biologics license application, including process patents.<sup>15</sup>
- Ensure that the Purple Book includes more complete data on FDA-licensed biological products, such as patents and exclusivities from the time of licensure going forward.<sup>16</sup>
- Direct the FDA to publish timely updates to the Purple Book.<sup>17</sup>
- Create a unified registry for drug and biological products that increases patent transparency and promotes timely approval of generics and biosimilars.<sup>18</sup>

## PRODUCT HOPPING

- *Drug Competition Enhancement Act*. This bipartisan bill would:
  - › Prohibit product hopping, providing the FTC with methods for enforcement.
- Direct the FDA to request that the brand manufacturer provide evidence on the incremental clinical value of a new patent and evaluate the claim prior to listing it in the Orange Book.
- Maintain and strengthen the ability to challenge patent validity under Patent and Trademark Office (PTO), including keeping the Inter Partes Review (IPR) process in place.

## CITIZEN'S PETITIONS

- *Stop STALLING Act*. In 2024, the Congressional Budget Office found the bill would reduce federal budget deficits by \$401 million over 10 years.<sup>19</sup> The bill was reintroduced in the 119th Congress. This bipartisan bill would:
  - › Penalize brand drugmakers from filing “sham” or baseless citizen’s petition to the FDA with the intent that the FDA’s review of the petition would delay the approval of a generic competitor.
- Strengthen the FDA’s authority to dismiss petitions and penalize non-meritorious filers by instituting time limits and associated penalties.<sup>20</sup>
- Improve the transparency of the FDA’s review of citizen petitions by requiring the agency to report more details about delays and the agency’s review process.<sup>21</sup>
- FDA should implement stronger procedural blocks, such as requiring that drug companies file their citizen petitions within a year after the generic company files its application or establishing that issues raised by petitions will be resolved on a separate timeline from the generic’s approval process.<sup>22</sup>



## ENDNOTES

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