How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing

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Introduction

In the United States, biosimilars represent a significant cost savings opportunity in the realm of pharmaceutical spending. Once they launch, biosimilars compete with some of the most expensive and widely used prescription drugs on the market — drugs known as biologics. But US biosimilars have seen sluggish market entry and uptake due to preexisting barriers to these products.[1] Some of the hurdles facing biosimilars are unintentional, while others are deliberately crafted by manufacturers of reference biologics to thwart competition.

Patent thickets represent potentially the most significant intentional barrier to biosimilars in the United States. This term describes how reference biologic manufacturers create a "thicket" of overlapping, weaker follow-on patents to the original patent for the purpose of keeping competitors from entering the market.

While patent thickets are a concern in other countries, they are a particularly serious problem in the United States because they are more prolific and larger in scale. Critics of patent thickets often point to their detrimental impact on US patients and payors, who stand to benefit from the savings that biosimilars can generate. These lost savings indeed are of great concern. But, as this paper highlights, patent thickets have another downside that is less well known: they create a barrier to the domestic manufacturing of biosimilars and associated employment opportunities for US workers.

[1] *See Alex Brill and Christy Robinson, "Steps to Reducing Barriers to Biosimilars in the United States," September 2018, available at www.getmga.com/wp-content/uploads/2018/09/BarriersToBiosimilars_September2018.pdf.*

BIOSIMILARS IN THE UNITED STATES

Biologics are medicines made from living cells and, as such, cannot be chemically manufactured like traditional "small-molecule" drugs. In 2010, a pathway was created for lower-cost versions of these expensive medicines to enter the US market. Through this regulatory pathway, biosimilars, as they are known, are approved by the Food and Drug Administration (FDA) as having no clinically meaningful difference from their reference biologics.

The US biosimilars market has been slow to develop. Today, the FDA has approved 29 biosimilars for nine reference products (*FDA, 2020*). Of these, 18 biosimilars (for seven reference products) have launched. But two-thirds of the biosimilars on the market have only been available since January 2019.

Barriers to biosimilars — including patent thickets, the topic of this paper — have inhibited a flourishing market. Today, less than 20 percent of the $211 billion biologics market is subject to competition from biosimilars (*IQVIA, 2020*). For biosimilars to reach their full potential in the United States, policymakers and stakeholders will need to work to remove or reduce unnecessary barriers.

Understanding Patent Thickets

Patents are an essential tool in protecting and incentivizing inventors and innovators. By keeping competitors at bay for a period of time (usually 20 years), patents permit their holders to recoup investment costs related to the development of their intellectual property and earn a return on their investment. However, abuse of the patent system, including the creation of patent thickets, leads to costly and inefficient monopolies. While patent thickets exist for products in other industries, prescription drugs — and reference biologics in particular — have proven to be popular targets of this strategy.

Biologics are often huge moneymakers, giving originators a strong incentive to protect their monopolies and profit streams. In the United States, originators have learned that it is relatively easy to create patent thickets that significantly extend the duration of monopolies.

HOW PATENT THICKETS ARE CONSTRUCTED

Patent thickets are created using the following strategy. In addition to patents on the biologic compound itself, originators obtain secondary patents, often long after the biologic is on the market. As healthcare research and advocacy organization I-MAK (*2020*) explains, "Patent applications are strategically staggered throughout the drug's life cycle in order to maximize the exclusivity period."

Secondary patents cover formulations, indications, dosages, routes or duration of administration, and other areas incidental to the product patents. In each incidental category, or "family," the originator will amass patents, often with minimal difference in wording of the patent claims. And, since each family provides 20 years of protection from the date of the filing of the first patent in that family, these tactics create a thicket that is both multi-layered and protracted. Without invalidating or designing around the multitude of secondary patents, a biosimilar manufacturer cannot bring its product to market.

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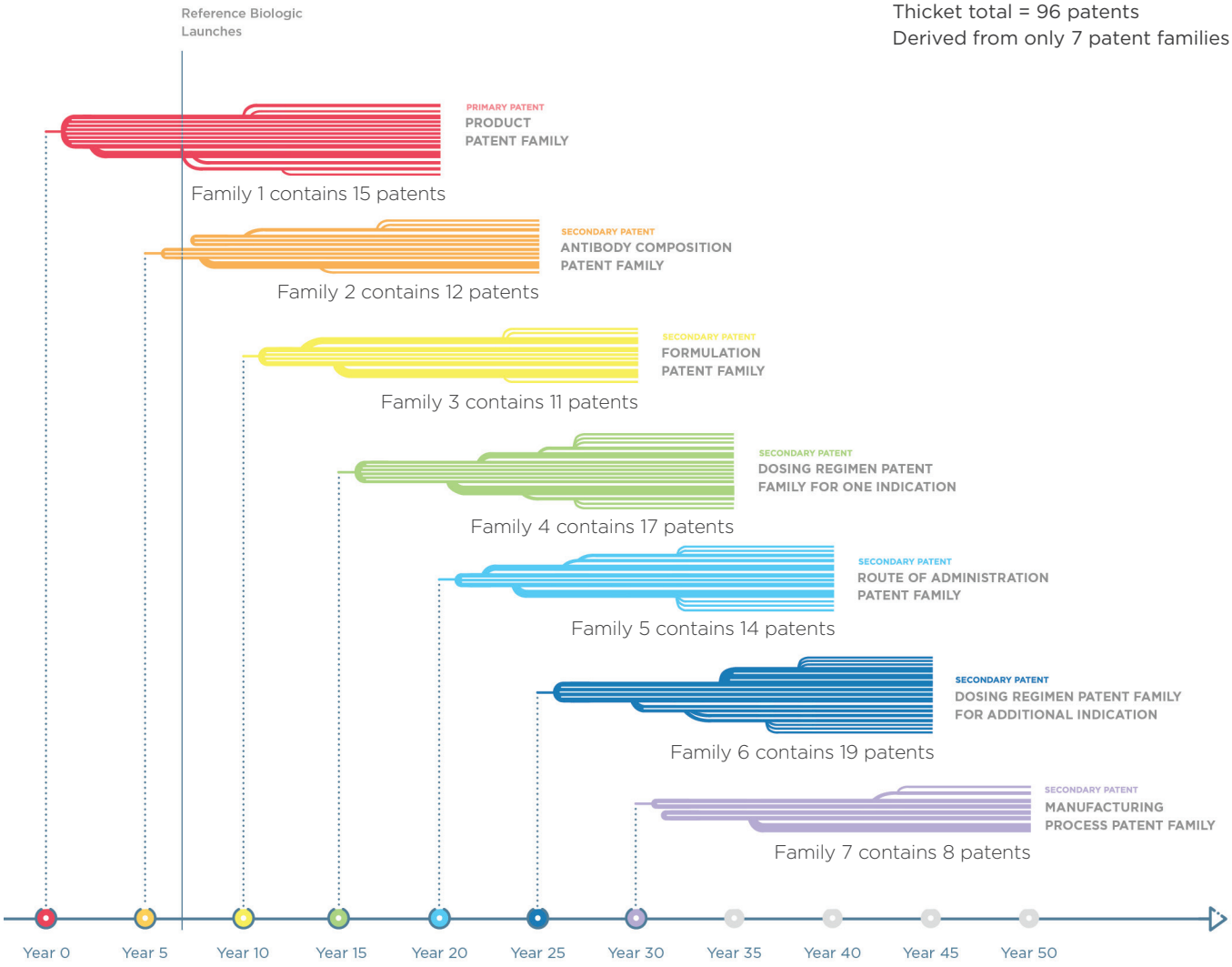
For an illustration of how a typical biologic patent thicket is constructed, see **Figure 1**. For an example of a real-world patent thicket currently being formed, see the accompanying case study on the patent thicket that Bristol Myers Squibb is in the process of assembling around its cancer product Opdivo®.

FIGURE 1. ILLUSTRATIVE EXAMPLE OF A BIOLOGIC PATENT THICKET



CASE STUDY:

The Growing Patent Thicket around Opdivo®

Opdivo® is a blockbuster cancer drug manufactured by Bristol Myers Squibb (BMS). It treats lung, kidney, liver, bladder, colorectal, head and neck, and esophageal cancers, as well as Hodgkin lymphoma and melanoma. In 2019, US sales were $4.3 billion (*BMS, 2020*).

Opdivo® is a relatively new biologic, having been approved by the FDA in December 2014, but there is clear evidence of a patent thicket being constructed, with 38 patent "families" thus far. Of these, 30 were filed after Opdivo® entered the US market. These families each contain multiple patent filings.

One of the 38 families covers the product patents on Opdivo®'s drug structure, and the rest comprise secondary patents, covering formulation, drug combinations, methods of treatment, dosing regimens, and other incidental aspects of the product. Additional patent families are likely to be filed, and US Patent and Trademark Office (PTO) rules permit the filings of an unlimited number of "child patents" within each family.

In Europe, a similar number of Opdivo® patent filings have been made, but far fewer have been granted. For example, one of the earliest filed method of treatment patent families already contains 15 granted US patents — each with claims that differ very little in wording from one another. In Europe, this same patent family has no granted patents and has received multiple rejections by the European Patent Office (EPO). Originators typically file patent applications throughout the lifetime of a drug, so many patent applications continue to be under consideration at the EPO and PTO. However, the PTO is granting far more Opdivo® patents than the EPO.

Several other blockbuster biologics compete with Opdivo®, and these products have patent thickets of their own, covering overlapping subject matter. For example, patent infringement litigations have arisen between the originators of Opdivo®, Keytruda®, and Tecentriq®. Eventually, biosimilars of Opdivo® will have to confront patent thickets belonging to several originators in order to enter the US market.

Impact and Magnitude of Patent Thickets in the United States

There is no mistaking the intent behind originators' efforts to obtain, on a single product, scores of patents with overlapping protections — many sought well after the product has launched. During his tenure as Food and Drug Administration (FDA) Commissioner, Scott Gottlieb (*2018*) described patent thickets around reference biologics as "purely designed to deter the entry of approved biosimilars."

As such, patent thickets have strictly negative consequences for US patients and payors, without the countervailing benefits that appropriate intellectual property protection offers. These negative consequences are all the greater because patent thickets have proven to be such an effective way for originators to preserve monopolies and continue to charge high prices.

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A recent analysis from the Biosimilars Council (*2019*) estimated the cost of patent thickets to US patients and payors by looking at the biosimilars that had been approved by the FDA but were unable to launch because of patent thickets. The analysis found that, from 2012 to 2018, the US healthcare system lost out on $7.6 billion that biosimilars of five reference biologics (Avastin®, Enbrel® Herceptin®, Humira®, and Rituxan®) could have saved. Of these five biologics, Enbrel® and Humira® — with 2019 US sales of more than $5 billion and nearly $15 billion, respectively — still do not have biosimilar competitors on the market. If left unchecked, patent thickets will continue to prevent savings from being realized on other biologics.

Demonstrating the scale of US patent thickets, a 2018 study from I-MAK documented the excessive number of patents that originators obtained on the 12 best-selling drugs in the United States, eight of which are biologics (Avastin®, Enbrel®, Eylea®, Herceptin®, Humira®, Lantus®, Remicade®, and Rituxan®). According to I-MAK (*2018*), the number of granted US patents on these eight biologics ranged from 41 (on Enbrel®) to 132 (on Humira®).

To better understand the sheer magnitude of patent thickets on US reference biologics, consider comparable patent litigation in Germany and the UK, the two largest European biologics markets, related to the 20 FDA-approved biosimilars that have European counterparts. The UK has seen only 16 patents asserted and Germany only one patent asserted compared to the 279 patents that have been asserted in the United States for these reference biologics. (See Section V for a more in-depth look at the drastically higher number of patent litigations in the United States compared with Germany and the UK, and a discussion of why patent thickets are a bigger problem in the United States.)

Factors Contributing to Patent Thickets

Certain factors within the US patent system facilitate originators' efforts to establish patent thickets around reference biologics. These include incentives and opportunities for originators to seek patents, costs and uncertainties for potential competitors in challenging patents, and longstanding issues at the US Patent and Trademark Office (PTO), among other factors.

INCENTIVES AND OPPORTUNITIES TO BUILD PATENT THICKETS

As mentioned above, originators have a strong incentive to amass as many patents as possible on reference biologics with high asset value. They also have ample opportunity to accumulate patents. There is no cap on the number of patent applications an originator can file for a single product, and patent applications can be filed long after a product is established on the market.

Originators face relatively low barriers in applying for patents, as the direct cost to obtain a patent and maintain it until it expires is typically less than $25,000. US patent applications for the eight best-selling biologics identified in I-MAK (*2018*) averaged 147 per product, with 53 percent of these applications resulting in patents.

To date, there is no statutory prohibition on creating a patent thicket to inhibit biosimilar competition (*Richards et al., 2020*). Lawmakers have lately made proposals aimed at curtailing this behavior, but, for now, it is entirely up to biosimilar manufacturers to clear or find ways to work around the scores of patents that originators are able to obtain.

COSTS AND UNCERTAINTIES FOR CHALLENGERS

Biosimilar manufacturers face substantial cost and uncertainty in challenging a patent, particularly compared to the ease with which originators can obtain patents. Patent litigation is time-consuming and costly. While legislation in 2011 created an avenue for challenging a patent at the PTO and avoiding the cost of a lawsuit, this is still an expensive endeavor. The process, known as inter partes review (IPR), has a median cost of $324,000 (*Richards et al., 2020*) and is more expensive when a biologic is in question — likely up to $1 million per IPR per patent.

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Also problematic is the fact that an IPR may go nowhere. After a petition for IPR is filed, it is submitted to the Patent Trial and Appeal Board (PTAB) within the PTO, but the PTAB can simply decline to institute review at its discretion.

Since 2015, the PTAB's rate of institution has been falling. In fiscal year 2016, 67 percent of petitions were instituted, dropping to 56 percent in fiscal year 2020 (*PTAB, 2020)*.

The timing of an IPR can also be tricky. In the United States, biosimilar applicants are hindered from filing IPRs early because a company that has not yet filed an application with the FDA may not have standing to appeal a negative IPR decision. Additionally, a company that files an IPR can lose standing to appeal if development of the drug at issue is stalled while the IPR appeal is pending.

A 2020 Federal Circuit case illustrates the risks for a biosimilar manufacturer in challenging a patent at an early stage. The case centered around Pfizer filing for IPR to challenge the validity of Chugai's patents relating to Ruxience®. Several of the IPRs failed, and Pfizer sought to appeal the decision to the Federal Circuit. The court noted that Pfizer failed to establish standing to appeal because, at the time the appeals were filed, Pfizer's biosimilar of Ruxience® had not received FDA approval. As discussed below, later challenges to patents face a denser thicket that has been able to grow while a biosimilar is in development.

SYSTEMIC PROBLEMS AT THE PATENT AND TRADEMARK OFFICE

There are numerous reasons why originators are able to obtain excessive numbers of patents at the PTO. Procedures and incentives are two of the most important reasons.

Procedures. The patentability rules used by the PTO make it easy to amass patents around a single invention. There is no limit to the number of "child patents" that can be filed from a single patent filing. And a loose approach to claim amendments allows patent owners to file child patents with only incrementally different claim wording. Objections to "double-patenting" (patenting the same invention twice) are relatively easy to circumvent. Moreover, even if a US patent examiner issues a final rejection against a patent application, a patent applicant can pay a fee and file a "request for continued examination" an unlimited number of times.

Incentives. The PTO evaluates examiner performance based on a "count system." Because examiners receive a higher count for a patent grant than for other actions, examiners have an incentive to work with applicants to obtain the higher count value.

Experts and scholars have documented long-standing problems at the PTO that result in the issuance of invalid patents (see, for example, Lemley and Sampat (*2012*) and Ford (*2013*)). On reference biologics specifically, FY 2013–2018 data published by the PTAB on petitions challenging biologic patents show that fewer than a quarter of instituted claims were found to be patentable (*Ankenbrand and Repko, 2019*).

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This is not to say that patent examiners are individually to blame for the rise of patent thickets. But the reality is that the PTO is an imperfect arbiter of intellectual property, and originators are able to capitalize on this, leaving biosimilar manufacturers — and consumers — to bear the burden.

US Patent Thickets in Context

Patent thickets around reference biologics are a much more significant problem in the United States than they are in other countries. Comparing patent landscapes in other major markets has some limitations because the criteria and processes for granting and challenging patents can differ. But it is worth making some broad observations.

Consider reference biologic patents and related litigation in Germany and the UK compared to the United States. Germany and the UK are the two largest European biologics markets, and their patent litigation courts are among the most experienced in Europe.

To date, there are 20 biosimilars that have received FDA approval that have also been submitted to the European Medicines Agency. Across these 20 biosimilars, 279 patents have been asserted in the United States, 16 patents in the UK, and only one patent in Germany (see **Chart 1**). Looking at specific products, manufacturers of biosimilars of Herceptin® that did not settle with the originator prior to litigation have been sued on an average of 35 patents in the United States, while only five Herceptin® patents were asserted in the UK and only one in Germany. In the case of Rituxan®, the originator asserted an average of 32 patents in the United States against biosimilar applicants who did not have a pre-litigation settlement. In the UK, the originator asserted an average of three patents. No Rituxan® patents were asserted in Germany.

Several factors seem to contribute to the lower number of patents and the relative lack of patent litigation in Germany and the UK compared to the United States. First, some have argued that patent examination at the European Patent Office (EPO), and thus patents themselves, are of higher quality in Europe than in the United States For example, EPO President Benoît Battistelli has insisted that the EPO's lower rate of granting patents is indicative of the better quality of review and greater soundness of patents in Europe compared to the United States (*Chung, 2016*). If this is true, it would make sense that better quality control at the EPO would weed out lower-quality secondary patents.

CHART 1. PATENTS ASSERTED ACROSS 20 BIOSIMILARS: UNITED STATES, UK, AND GERMANY

Second, in Europe, patents can be challenged in the first nine months through opposition procedures at the EPO, or later through litigation (*Moorkens et al., 2020*). Opposition procedures are inexpensive, with a current fee of €815. This allows invalid patents that have been granted to be cleared quickly. In addition, in Europe, third parties can challenge the validity of patents at any stage during the development of their biosimilar.

The equivalent tool in the United States is IPR, discussed above. However, compared to European patent oppositions, IPR is less accessible to third parties, in particular due to issues with standing. As noted earlier, biosimilar applicants in the United States may not be able to appeal a negative validity decision until their biosimilar application has been filed at the FDA, which can be 10 years or more following patent grant.

Consider, for example, biosimilars of Herceptin®. Patents covering Herceptin® were filed in the United States and Europe in the early 1990s. The first EPO opposition was filed in 1996. Nine more European patents were opposed between 2000 and 2010, seven were opposed between 2011 and 2016, and six were opposed in 2017 and 2018. In the United States, the Herceptin® patent thicket was able to grow unchecked by third-party challenges until the first IPR was filed in 2015. Eight IPRs were filed in 2016, and 33 IPRs were filed in 2017. Despite these efforts, the first Herceptin® biosimilar applicant was sued under 40 US patents in January 2018, and three other applicants were sued under 40, 37, and 21 US patents, respectively.

Impact of Patent Thickets on Domestic Manufacturing

One consequence of patent thickets in the United States that is not well understood is the barrier they create to the domestic production of biosimilars. This is particularly important in light of the current interest among some policymakers, Democrats and Republicans alike, in encouraging more domestically produced prescription drugs. “Buy American” is only a viable option if manufacturers can produce in America without infringing US patents.

One consequence of patent thickets in the United States that is not well understood is the barrier they create to domestic production of biosimilars.

At present, drug manufacturers are at legal risk if they manufacture or stockpile biosimilars for commercial launch in the United States before patents expire or patent litigation is resolved. Biosimilar manufacturer Hospira learned this the hard way in *Amgen v. Hospira* when Amgen was awarded $70 million in damages for Hospira’s

infringement of an Epogen® process patent, despite Hospira not actually selling its biosimilar on the US market (*Ainsworth and Bruns, 2020*).

Because manufacturing a biosimilar in preparation for market entry requires up to 12 months, a biosimilar firm needs to manufacture its product in a country where the patent situation is predictable. The vast majority of the time, this will not be the United States. Once manufacturing is up and running, a biosimilar firm is unlikely to move its operations to another country, as it can take years to transfer the technology, adding risks and costs. In other words, the jobs and economic activity associated with manufacturing US biosimilars will often be located outside the United States.

The European Union, in an effort "to foster the competitiveness of EU producers of generic medicines and biosimilar products," created an exception in 2019 that allows production and stockpiling of generic and biosimilar medicines before expiration of a supplementary protection certificate (a certificate that extends patent life in Europe) (*European Council, 2019*). Over 10 years, the new EU regulation is expected to result in net export sales of biosimilars and generic medicines of more than €1 billion annually, and potentially 20,000–25,000 jobs (*Ibid.*).

As patent attorneys who called attention to this consequence of the US patent system said in 2018, "While there may be other reasons not to manufacture in the U.S., there is no reason why the U.S. patent system should effectively force companies to manufacture abroad" (*Rein et al., 2018*).

Establishing an exception policy in the US like the one the EU recently instituted would reduce some of the barriers to manufacturing biosimilars in the United States but may be insufficient because of the layering and overlapping of patents in the United States described earlier. Despite the many advantages of manufacturing in the United States, uncertainty about a biosimilar manufacturer's ability to avoid patent infringement in the United States will still drive manufacturing to foreign markets.

While many reference biologics are manufactured domestically, market research expert Dawn Ecker predicts that, in the next few years, Europe will overtake the United States as the leader in biologic manufacturing (*CPhI, 2019*). This illustrates both the current success of US biologic manufacturing and a concerning trend for those interested in growing the US share of global biologic production. It also suggests that technical, regulatory, and manufacturing costs in the US are not insurmountable barriers and lends support to the view that domestic biosimilar manufacturing may be strongly deterred by patents.

Policy Options

Researchers and experts have looked at a range of reform options to address patent thickets. Some proposals — like giving the PTO more resources and creating higher standards for patents — are broader and would address other misuses of the patent system in addition to patent thickets (*Richards et al., 2020*).

More radical proposals include "consolidating all drug patents and exclusivities into one longer, but transparent and flexible exclusivity period" and letting the FDA grant "bonus" exclusivity periods for significant improvements in a drug (*Wu and Cheng, 2020*). In the last several years, members of Congress on both sides of the aisle have become increasingly aware of and concerned about patent thickets, but legislative proposals to address patent thickets have thus far not been enacted.

The problem of patent thickets is multifaceted, and there is not one easy solution. Nor have all the policy options been introduced or considered. Broadly, what will help ease the problem of patent thickets will be reforms at the PTO that promote better patents and IPRs, anti-gaming policies that deter anticompetitive patent practices by originators, and reasonable limits on the number of patents that can be asserted against biosimilar competitors. Among the benefits of these reforms could be substantial healthcare savings and a greater willingness of biosimilar manufacturers to locate their facilities in the United States.

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Conclusion

Prescription drug spending is a concern to many stakeholders in the United States, and this is reflected in the manifold policy proposals in recent years aimed at bringing down drug prices. Though well-intentioned, many of these proposals unhelpfully focus on the symptoms of a larger problem in the United States instead of the problem itself. For example, the US Department of Health and Human Services recently issued an interim final rule moving to a most favored nation (MFN) model for reimbursement of drugs in Medicare Part B. Under this rule, providers in Medicare Part B will be reimbursed at "the lowest price that drug manufacturers receive in other similar countries" (*CMS, 2020*). At present, courts have issued an injunction preventing this rule from taking effect, and stakeholders await a decision by the new administration regarding this policy.

The MFN model and other drug pricing proposals miss the bigger picture. All of the top 10 drugs in Part B are biologics (*MedPAC, 2020*), and biologics have been driving growth in drug spending in the United States (*IQVIA, 2019*). Competition in the biologic market remains limited, and patent thickets represent a huge impediment to the ability of lower-cost biosimilars to come to market in the years ahead. Policymakers must understand that, unless patent thickets are dramatically curtailed, the problem is only going to get worse. As this paper has detailed, patent thickets not only keep US drug prices high, but also discourage domestic manufacturing of biosimilars.

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