UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, *et al.*,

Defendants.

Civil Action
No. 1:24-cv-810-NYW-SBP

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT

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INTRODUCTION

Innovative medicines have enhanced and extended the lives of countless Coloradans. Recognizing the enormous investment of time and money needed to discover and develop these novel treatments, Congress rewarded those who bring new medicines to market with a period of patent exclusivity and pricing discretion. As binding precedent makes clear and numerous scholars have observed, the economic incentives provided by the federal patent system are crucial to Congress's objective of promoting pharmaceutical research and development.

One such medicine, Amgen's pioneering drug ENBREL® (etanercept), provides life-changing relief to thousands of Coloradans who suffer from arthritis and other autoimmune diseases. Enbrel redefined the clinical course of moderate to severe rheumatoid arthritis, allowing many who would have endured intensifying pain, deterioration, disfigurement, and declining mobility to live years or even decades with less pain and greater function. Amgen's patents provide Enbrel with a time-limited period of exclusivity, enabling Amgen to obtain a fair return on its investment.

Although patent protection allows manufacturers to charge higher prices for innovative drugs during the life of the patent, manufacturers offer many programs that support patients who may have difficulty affording their medicines. For example, for more than 20 years Amgen has sponsored the Amgen Safety Net Foundation, a nonprofit patient assistance program that helps eligible patients in the United States gain access to qualifying Amgen medicines. In 2023 alone, the Foundation provided

$2.5 billion worth of drugs to eligible uninsured or underinsured patients at no cost.[1]

Nevertheless, Colorado enacted legislation in 2021 establishing a "Prescription Drug Affordability Review Board" with sweeping power to deem drugs "unaffordable for Colorado consumers" and subject those drugs to price controls. *See* Colo. Rev. Stat. § 10-16-1401 *et seq*. ("the Act"). In February 2024, after expressing concern that Enbrel's patents protect it from biosimilar competition, the Board declared Enbrel "unaffordable" and voted to "select Enbrel for establishment of an upper payment limit." The Board thus decided to restrict the maximum amount that can be billed or paid for units of Enbrel dispensed or distributed in Colorado. The Board will conduct hearings this Fall to decide the precise payment limit it will impose.

Colorado's price-control scheme is unconstitutional for at least four reasons. ***First***, the federal patent laws preempt Colorado's attempt to regulate the price of patented drugs like Enbrel. To incentivize the immense risk-taking and investment necessary to discover and develop new medical treatments, Congress enacted and has repeatedly refined the federal patent laws, often doing so with a special focus on pharmaceutical patents. This carefully calibrated federal patent system rewards pharmaceutical innovation with a period of market exclusivity and the ability to set prices during that period. Colorado's price-control regime disrupts that finely tuned system by allowing five members of a state-created board to strip away the very

[1] *See* Amgen Safety Net Found., *About*, https://www.amgensafetynetfoundation.com/about.html; Amgen, Environmental, Social & Governance Report 2023, at 10, *available at* https://www.amgen.com/responsibility/environmental-social-and-governance-report.

economic rewards and incentives that Congress sought to provide. The Federal Circuit—whose case law is controlling on issues of patent preemption—has held that a state may not impose price controls on patented drugs, because allowing states to limit "the pecuniary rewards stemming from the patent right" would be "contrary to the goals established by Congress in the patent laws." *Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372–74 (Fed. Cir. 2007).

Second, Colorado's scheme violates the Due Process Clause of the Fourteenth Amendment because the statute does not provide any meaningful standards for the Board to apply either when determining whether a drug is "unaffordable for Colorado consumers" or when setting an upper payment limit. The statute contains a long and non-exclusive list of factors the Board may consider, but it neither defines "unaffordable" nor provides any guidance about how the Board should weigh those factors. Without any meaningful standards to constrain the Board's decision-making, manufacturers are deprived of the *sine qua non* of due process—the opportunity to be heard at a meaningful time and in a meaningful manner. The Act also violates the more specific due-process principles that apply to administrative price-control schemes. Because of the serious constitutional concerns they raise, courts have required such schemes to include standards and procedures to guard against arbitrary or discriminatory price-setting and to ensure that regulated parties can earn a reasonable return on their investments. The Act lacks those essential safeguards and leaves regulated parties subject to the whims of the Board.

Third, Colorado's scheme is preempted insofar as the "upper payment limit" applies to federal payors such as Medicare, TRICARE, the Veterans Health Administration, and the Federal Employees Health Benefits Program. Under the Supremacy Clause, states lack the power to regulate federal government activities, and federal law preempts state laws that interfere with the federal government's ability to control its own payment and coverage decisions.

Fourth, Colorado's attempt to control prices in out-of-state transactions violates the Commerce Clause. It is well-established that states cannot directly regulate commerce that occurs entirely out of state. The Act violates that extraterritoriality principle because the "upper payment limit" applies to transactions that occur outside Colorado's boundaries, so long as the drug is ultimately dispensed or distributed in Colorado.

BACKGROUND

A. The Federal Patent System

The discovery and development of new prescription drugs is of vital importance to public health. Innovative medicines save lives and improve patients' quality of life, frequently offering new hope for diseases that were once thought untreatable. But the process of developing new drugs—conducting cutting-edge research, navigating the lengthy FDA approval process, and bringing the drugs to patients in need—is time-consuming, uncertain, and expensive. The average cost of bringing a single new

drug to market is commonly estimated to be more than $2 billion,[2] the process takes an average of 10 to 15 years,[3] and only about 1 in 5,000 potential new drugs obtains approval and reaches patients.[4] Of the medicines approved for patient use, only about 20% ever generate enough revenue to cover their own development costs.[5]

To reward and incentivize the risk-taking and investment necessary for technological innovation, Congress has long relied on the federal patent system. The Constitution vests in Congress the power to grant authors and inventors exclusive rights to their creations for limited times "[t]o promote the Progress of Science and useful Arts." U.S. Const. art. I, § 8, cl. 8. Exercising that constitutional prerogative, Congress has established a comprehensive national system for the granting and maintenance of patents. *See* 35 U.S.C. § 1 *et seq.* Pursuant to the Patent Act, a patent grant confers "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. *Id.* § 154(a)(1).

Under the system Congress designed, "the fundamental purpose of the patent grant" is to "create[] an incentive for innovation" by providing "economic rewards

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[2] Stephen Ezell, Info. Tech. & Innovation Found., Ensuring U.S. Biopharmaceutical Competitiveness, at 30 (July 2020), *available at* https://www2.itif.org/2020-biopharma-competitiveness.pdf.

[3] GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 20, 2019), *available at* https://www.gao.gov/assets/gao-20-215sp.pdf.

[4] Paul Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021), https://doi.org/10.1016/j.csbj.2021.08.011.

[5] Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 665 (2016).

during the period of exclusivity." *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). Once the exclusivity period expires, others may enter the market and compete with the patent holder, driving down the product's costs. The patent system thus embodies "a careful balance" between "the need to promote innovation" by enabling innovators to set their own prices during the patent term, and the benefits of greater affordability that flow from competition after the term expires. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Congress has deliberately fine-tuned that balance by specifying the duration of exclusivity periods and establishing procedures for adjusting them. *See* 35 U.S.C. § 154.

Congress has especially fine-tuned the rules governing pharmaceutical patents. In 1984, recognizing the unique challenges posed by the costly drug-development process, Congress enacted the Drug Price Competition and Patent Term Restoration Act (known as the "Hatch-Waxman Act"). The Hatch-Waxman Act extended the patent term for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18 (1984); *see* 35 U.S.C. § 156. The statute was designed to "promote medical breakthroughs and drug innovation by granting drug companies up to 5 more years of patent protection for new drugs" to "help compensate for the years of patent life lost" due to the protracted FDA approval process. Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

Congress has promoted competition after the expiration of an innovator drug's patent by creating pathways for competing products to obtain FDA approval. For chemically synthesized, small-molecule drugs, the Hatch-Waxman Act allows generic versions to receive FDA approval without the same level of clinical testing required for new brand-name drugs. *See* 21 U.S.C. § 355(j). For "biologic drugs" (large molecules made from living cells), such as Enbrel, a pathway for FDA approval of "biosimilars" was created by the Biosimilar Price Competition and Innovation Act of 2009 (the "BPCIA"). *See* 42 U.S.C. § 262(k).

B. Colorado's Prescription Drug Price-Control Regime

In the Act, Colorado seeks to strike its own balance, which is different from the one Congress chose. The Act's stated purpose is to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1). To achieve that goal, the Act creates a Prescription Drug Affordability Review Board composed of five members appointed by the governor. *Id.* § 10-16-1402. The Board is directed to "[p]erform affordability reviews of prescription drugs" and "[e]stablish upper payment limits for prescription drugs." *Id.* § 10-16-1403(1). An "[u]pper payment limit" is defined as "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the prescription drug." *Id.* § 10-16-1401(23).

As an initial step, the Board identifies, based on certain cost-related criteria, a

list of prescription drugs eligible for an affordability review. *Id.* § 10-16-1406(1); 3 Colo. Code Regs. § 702-9:3.1(C). Next, the Board decides which eligible drugs to select for an affordability review. In making that determination, the Board considers (a) "the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale"; (b) "aggregated data" regarding costs, pricing, expenditures, utilization, and "[h]ealth equity impact"; (c) input from the Board-appointed Prescription Drug Affordability Advisory Council; and (d) "the average patient's out-of-pocket cost for the prescription drug." Colo. Rev. Stat. § 10-16-1406(2); 3 Colo. Code Regs. § 702-9:3.1(D).

Once a drug is selected for an affordability review, the Board's task is to "determine whether use of the prescription drug" is "unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). The statute does not define "unaffordable for Colorado consumers" or otherwise provide any legal standard to constrain the Board's discretion. Instead, it instructs the Board to "consider," "to the extent practicable," a broad and nonexclusive list of factors, including: (a) the drug's "wholesale acquisition cost"; (b) the "cost and availability of therapeutic alternatives"; (c) "[t]he effect of the price on Colorado consumers' access to the prescription drug," (d) the drug's "relative financial effects on health, medical, or social services costs"; (e) the typical "patient copayment or other cost sharing" for the drug under "health benefit plans issued by carriers in the state"; (f) the "impact on safety net providers if the prescription drug is available through section 340B of the federal 'Public Health

Service Act'"; (g) "[o]rphan drug status"; (h) input from "[p]atients and caregivers" and "[i]ndividuals who possess scientific or medical training"; (i) "[a]ny other information that a manufacturer, carrier, pharmacy benefit management firm, or other entity chooses to provide"; and (j) "[a]ny other factors as determined by rules promulgated by the [B]oard." *Id.* § 10-16-1406(4). The Board "may" also "consider any documents and information relating to the manufacturer's selection of the introductory price or price increase," including documents and information related to the drug's "[m]arket competition and context." *Id.* § 10-16-1406(6). The Board has issued a regulation listing a handful of additional factors it will consider, including (i) "estimated manufacturer net-sales or net-cost amounts," (ii) undefined "health inequities in priority populations," (iii) unspecified "analyses" conducted by the state Department of Health Care Policy and Financing, and (iv) information regarding "[n]on-adherence" or "utilization management restrictions" for the drug in question. 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). Neither the statute nor the regulation specifies how any of these factors bears on the ultimate question of "affordability" or how much weight the Board should give to any particular factor.

If the Board determines in its discretion that a drug is "unaffordable for Colorado consumers," it may establish an "upper payment limit." Colo. Rev. Stat. § 10-16-1407(1)(a). Rather than prescribe a methodology for setting that limit, the Act says only that any methodology chosen by the Board "must include consideration of" the cost of "administering," "dispensing," and "distributing" the drug, the drug's

status on FDA's "shortage list," and any impact on "older adults and persons with disabilities"; must not "consider research or methods" that "discount[] the value of a life because of an individual's disability or age"; and must allow pharmacies to charge "reasonable fees" for dispensing the drug. *Id.* § 10-16-1407(2)–(4). Otherwise, the Board is free to adopt whatever methodology it wishes.

The Board has promulgated a regulation purporting to "establish the methodology … for the Board to establish upper payment limits." 3 Colo. Code Regs. § 702-9:4.1(B). But the regulation does not specify a methodology. Instead, it merely states that the Board "shall review" the factors set forth in the statute. 3 Colo. Code Regs. § 702-9:4.1(C)(2). The regulation elaborates on some of those factors without providing additional specificity: For example, it states that "[t]o approximate prescription drug costs," the Board "may consider" "one or more price and cost metrics" that "include but are not limited to" a list of 10 different measures. *Id.* § 702-9:4.1(C)(2)(a). Despite identifying a variety of data points the Board will "consider" or "review," neither the statute nor the regulation explains what methodology, if any, the Board will apply in choosing the amount of an upper payment limit.

C. Amgen's Patent-Protected Drug Enbrel

Enbrel, first approved by the FDA in 1998, is a groundbreaking injectable medicine used to treat certain autoimmune diseases, such as rheumatoid arthritis and psoriatic arthritis. Compl. ¶ 50. Enbrel can help patients with moderate to severe rheumatoid arthritis or psoriatic arthritis reduce joint pain, avoid permanent joint

damage, and dramatically improve their physical function and overall quality of life. *Id.* The active ingredient in Enbrel is a fusion protein called etanercept, which works by attaching to a protein in the body called "tumor necrosis factor" (TNF). *Id.* ¶ 51. When a patient's immune system produces too much TNF, it may lead to inflammation that causes pain, swelling, and joint damage. *Id.* By attaching to TNF, Enbrel inhibits TNF's inflammatory activity. *Id.*

Enbrel is covered by a number of United States patents, including U.S. Patent No. 8,063,182 ("the '182 patent"), which is directed to etanercept and was issued on November 22, 2011, and U.S. Patent No. 8,163,522 ("the '522 patent"), which is directed to methods of making etanercept and was issued on April 24, 2012. Compl. ¶ 52. Those two patents limit competing etanercept biosimilar products from entering the market until 2029 at the earliest. *Id.* ¶ 53. Plaintiff Immunex Corporation is the manufacturer of Enbrel and the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell Enbrel. *Id.* ¶¶ 17, 54. Immunex has granted Plaintiff Amgen Manufacturing, Limited ("AML") an exclusive sublicense to the '182 and '522 patents to manufacture and sell Enbrel, and AML has invested heavily to ensure a safe and reliable supply of Enbrel. *Id.* ¶¶ 18, 54. Both Immunex and AML are subsidiaries of Plaintiff Amgen Inc. This brief refers to Plaintiffs collectively as "Amgen."

D. The Board's Proceedings Against Enbrel

On June 9, 2023, the Board approved the final list of prescription drugs eligible

for affordability reviews. The list included 604 drugs that, according to the Board, met one or more of the statutory eligibility criteria.[6] On August 4, 2023, the Board selected five drugs for affordability reviews, including Enbrel. All of the selected drugs were brand-name drugs covered by unexpired patents.[7]

On February 9, 2024, the Board published its draft affordability review report for Enbrel. Compl. Ex. B. Totaling 499 pages, the report purported to discuss "information from the fifteen statutory and regulatory components the Board considers as part of an affordability review," *id.* at 3, but it followed no discernable methodology. It did, however, highlight Enbrel's patents as a reason for deeming Enbrel "unaffordable" and subjecting it to an upper payment limit. The report observed that "Enbrel has patent protection and is protected from biosimilar competition" due to "patents that prevent the introduction of biosimilar products" until 2029. *Id.* at 26. In contrast, the report noted, "[t]wo of Enbrel's therapeutic alternatives, Humira and Remicade, have recent FDA-approved biosimilar products," and "there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets." *Id.*

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[6] Colo. Div. of Ins., *Colorado PDAB 2023 Eligible Drug Dashboard* (Oct. 19, 2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/0_Navigation?publish=yes ("Drug 'Lookup' Tool").

[7] The other drugs selected were Cosentyx, Genvoya, Stelara, and Trikafta. Each was determined by the Board to be covered by at least one unexpired patent, as the Board acknowledged in its reports for those drugs (which are available at https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

Further emphasizing Enbrel's patent protection, the report included an appendix section devoted to "Patents and Exclusivity." *Id.* at C-9–C-11. The report explained that "[e]valuating patents and exclusivity can be helpful in understanding potential access concerns, because there is evidence that such intellectual property rights can be associated with increased drug prices." *Id.* at C-9. Having identified federal patent rights as a key factor affecting drug prices during the patent term, the report catalogued Enbrel's various patents and highlighted two that it stated currently "prevent the introduction of biosimilar products." *Id.* The report stated that Enbrel's '182 and '522 patents are "'core'" patents that are "considered to be quite strong" and "make the creation of a non-infringing biosimilar drug nearly impossible." *Id.* at C-11. The report noted that "Amgen has protected Enbrel through litigation of its patents in U.S. courts" and that multiple courts had upheld Enbrel's '182 and '522 patents against challenges from potential competitors seeking to market biosimilar drugs prior to the expiration of those patents in 2029. *Id.*

One week later, on February 16, 2024, the Board held a meeting at which it voted to declare that Enbrel is "unaffordable for Colorado consumers." 2/16/24 Mtg. Tr. 103:20-105:18.[8] One member remarked that even though one of Enbrel's therapeutic alternatives had historically been more expensive—in fact, it had topped the Board's list of the "top 10 highest spend eligible drugs," *see* Compl. Ex. C—the

[8] Video recordings of the February 16 and 23 meetings are available at https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board, and transcripts are attached for the Court's convenience.

Board selected Enbrel for an affordability review because unlike Enbrel, the other drug had recently gone off-patent and become subject to biosimilar competition:

> BOARDMEMBER CATHERINE HARSHBARGER: … I think in the graphs that we saw in our report, Humira cost-wise isn't cheaper, I guess is the way I'd put it; it's very expensive as well.
>
> BOARDMEMBER AMY GUTIERREZ: Back in 2022, Cathy, yes. But … whenever something goes biosimilar … that competition lowers the price. … [W]ith this drug … the biosimilars didn't become available until 2023.
>
> CHAIR GAIL MIZNER: And as you may recall, we actually decided not to do an affordability review on Humira because of those biosimilars that had become available.
>
> BOARDMEMBER CATHERINE HARSHBARGER: Right, right, okay.

2/16/24 Mtg. Tr. 33:16-34:11.

On February 23, 2024, the Board held a meeting at which it voted to adopt the final affordability review report for Enbrel, which included the conclusion that Enbrel is "unaffordable for Colorado consumers." 2/23/24 Mtg. Tr. 21:06-22:11. The Board then separately voted to "select[] Enbrel for establishment of an upper payment limit." *Id.* at 36:13-37:3. The Board has scheduled rulemaking hearings for September 6, October 18, and December 6 to determine the amount of that limit.

The Board's final report for Enbrel was made publicly available on March 21, 2024. In a new section titled "Board Deliberation and Vote Summary," the report reiterated the Board's finding that Enbrel is "unaffordable for Colorado consumers" and listed factors the Board had considered in reaching that determination, including

"availability of biosimilars." Compl. Ex. D at 2–3. The final report was otherwise identical to the draft in all relevant respects, including the discussion of Enbrel's patents. *See id.* at 25 and C-11–C-13.

On March 22, 2024, Amgen brought this action seeking declaratory and injunctive relief with respect to the constitutionality of the Act. Defendants are the Chair and members of the Board, the Commissioner of the Colorado Division of Insurance, and the Colorado Attorney General, all in their official capacities.

ARGUMENT

Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The parties agree that Amgen's constitutional claims raise legal questions that may properly be resolved on summary judgment, without the need for discovery or trial. ECF No. 18 at 2. For the reasons set forth below, Amgen is entitled to summary judgment on each of its claims.

I. Colorado's attempt to impose price controls on Enbrel conflicts with the federal patent laws.

1. Under the Constitution's Supremacy Clause, federal statutes are "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. A "fundamental principle of the Constitution" is thus that "Congress has the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). "Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." *Tuck v. United States*, 2022 WL 833367, at *6 (D. Colo. Mar. 21, 2022)

(Wang, J.) (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)). Preemption is therefore warranted not only when Congress has expressly preempted state legislation or occupied an entire regulatory field, but also when state law stands as "'an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* at *8 (quoting *Mt. Olivet Cemetery Ass'n v. Salt Lake City*, 164 F.3d 480, 486 (10th Cir. 1998)). This inquiry "ranges beyond the literal text" of the federal statute and requires an examination of its "'purpose and intended effects.'" *BIO*, 496 F.3d at 1372 (quoting *Crosby*, 530 U.S. at 373).

Although Tenth Circuit precedent is binding on other issues in this case, "Federal Circuit law governs whether federal patent law preempts … state law." *Kim v. Kettell*, 2023 WL 6248878, at *8 (D. Colo. Sept. 26, 2023) (citing *Tavory v. NTP, Inc.*, 297 F. App'x 976, 982 (Fed. Cir. 2008)); *see Vermont v. MPHJ Tech. Invs., LLC*, 803 F.3d 635, 643–47 (Fed. Cir. 2015) (noting Federal Circuit has jurisdiction when party seeks to enjoin state law "on grounds that it is preempted by the patent laws").

2. In enacting the federal patent laws, and especially the laws governing pharmaceutical patents, Congress has long sought to achieve a "careful balance" between competing interests. *Bonito Boats*, 489 U.S. at 146. On the one hand, Congress has recognized "the need to promote innovation" through economic incentives by enabling innovators to earn greater profits during the term of the patent. *Id.* On the other hand, Congress has sought to promote greater affordability by encouraging competition after a patent term expires. *Id.* Congress fine-tunes the

proper balance between economic incentives for innovation and affordability by specifying the duration of patent exclusivity periods and establishing procedures for their adjustment. *See* 35 U.S.C. § 154. "Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *BIO*, 496 F.3d at 1373.

The patent system thus "embodies a carefully crafted bargain" that rewards the creation and disclosure of new technological advances with "the exclusive right to practice the invention for a period of years." *Bonito Boats*, 489 U.S. at 150–51. Federal law does not grant innovators that exclusivity for its own sake. Rather, as the Constitution makes clear, the right to exclude is intended "[t]o promote the Progress of Science and the useful Arts." U.S. Const. art. I, § 8, cl. 8. And the principal mechanism by which the right to exclude accomplishes that aim is by enabling the patent-holder to set its own prices during the patent term, and thus to make more profit than it would without that right. As the Federal Circuit has explained:

> The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

King Instruments, 65 F.3d at 950. The "pecuniary rewards stemming from the patent right" are especially important to incentivize the costly research and development that drives pharmaceutical innovation. *BIO*, 496 F.3d at 1372; *see also Sanofi-*

Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 (Fed. Cir. 2006) (noting that patents "provide[] incentive to … innovative drug companies to continue costly development efforts"); Iain Cockburn & Genia Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, 25 Expert Op. on Therapeutic Pat. 739, 739 (2015) (explaining that patents "have long been considered essential to prescription drug development" due to "the costly, lengthy, and risky nature of innovative [pharmaceutical] research and development").

Congress has accordingly taken particular care to weigh competing interests, and to bolster incentives for innovation, in the pharmaceutical field. As discussed above, the Hatch-Waxman Act extended the patent term for pharmaceutical inventions to "create a significant, new incentive" that "would result in increased expenditures for research and development, and ultimately in more innovative drugs." H.R. Rep. No. 98-857(I), at 18. These strengthened protections were designed to compensate manufacturers for the time spent in clinical trials and the lengthy federal approval process. *See id.*; Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

Congress's deliberations on the Hatch-Waxman Act confirm the "central role of enhanced profits in the statutory incentive scheme." *BIO*, 496 F.3d at 1373. As the House Committee on Energy and Commerce observed, "[p]atents … enable innovators to obtain greater profits than could have been obtained if direct competition existed," and "[t]hese profits act as incentives for innovative activities."

Id. (quoting H.R. Rep. No. 98-857(I), at 17); *see also* 130 Cong. Rec. 15,847 (1984) (statement of Senator Hatch) (noting that the legislation "add[s] stimulus for research on new drugs … through an extension of patent life"); 130 Cong. Rec. 24,427 (1984) (statement of Representative Waxman) (explaining that a patent gives the holder "the ability to charge" higher prices until the patent expires and "competition … bring[s] about the result of a lower price for the consumer").

In keeping with those efforts, Congress has also sought to promote affordability by streamlining the FDA approval process for copycat drugs—but, importantly, only *after* the patent term expires. Congress created an approval pathway for generic small-molecule drugs in the Hatch-Waxman Act, *see* 21 U.S.C. § 355(j), and for more complex biosimilar drugs in the BPCIA, *see* 42 U.S.C. § 262(k). Congress has thus struck an intentional balance, ensuring that those who develop innovative medicines are rewarded with a period of federal patent exclusivity and pricing discretion, while encouraging lower prices through competition after the patent term ends.

3. Colorado's new price-control regime for prescription drugs, which does not contain any exemption for patented drugs like Enbrel, is preempted because it frustrates the purposes and objectives of the federal patent laws. Colorado seeks to restrain what it calls "excessive" costs for patented prescription drugs by delegating power to a state board to declare them "unaffordable" and subject them to "upper payment limits." Colo. Rev. Stat. §§ 10-16-1403(1), -1406(3). Colorado's approach would replace the "dictates of the marketplace," *King Instruments*, 65 F.3d at 950,

with the dictates of the Board. And it would upset the balance Congress struck between innovation and affordability by reducing the "size of the carrot" Congress provided in the patent laws—*i.e.*, the economic rewards that are part and parcel of patent ownership. *Id.* By undermining the profit incentives that are so central to Congress's design, the Act impermissibly "re-balance[s] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *BIO*, 496 F.3d at 1374; s*ee Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1305–06 (Fed. Cir. 2003) ("Through the federal patent laws, Congress has balanced innovation incentives against promoting free competition, and state laws upsetting that balance are preempted.").

The Federal Circuit recognized as much in *BIO*, where it struck down a similar price-control law enacted by the District of Columbia. Like the law at issue there, Colorado's statute "is a clear attempt to restrain" what the state considers "excessive prices" for patented drugs, thereby "diminishing the reward to patentees in order to provide greater benefit to [in-state] drug consumers." 496 F.3d at 1374. Congress, however, has already tailored federal patent law to achieve what it considers "the best balance" between the competing interests in rewarding innovation and promoting affordability. *Id.* at 1373. Colorado's attempt to reweigh those competing interests "is contrary to the goals established by Congress in the patent laws." *Id.* at 1374. A state cannot take it upon itself to "second-guess" Congress's design by preventing a patent owner or licensee from charging prices that reflect its federally

guaranteed patent rights. *Id.* (quoting *Bonito Boats*, 489 U.S. at 152). "The underlying determination about the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress." *Id.*

For the same reason, courts have held that state-law claims for unjust enrichment or unfair competition cannot be used as a vehicle to challenge patent-holders' pricing decisions. *See, e.g.*, *Se. Penn. Transp. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) (explaining that plaintiffs may not use state law to challenge manufacturer's "exercise of its exclusive patent rights to make pricing decisions" (footnote omitted)); *SanDisk Corp. v. Kingston Tech. Co.*, 863 F. Supp. 2d 815, 835 (W.D. Wis. 2012) (claim challenging "discriminatory pricing" was preempted because "policy decisions about the fair use of patents fall[] to Congress"). "Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing [a manufacturer] to lower its prices" for "the sale of its patented drugs." *Gilead*, 102 F. Supp. 3d at 703. So too, Colorado's attempt to use state law to force Amgen to charge lower prices for its patented drug "stands as an obstacle to the federal patent law's balance of objectives as established by Congress," *BIO*, 496 F.3d at 1374, and is therefore preempted.

4. The conflict with federal law is especially stark because the Board has deliberately targeted Enbrel based on its patent protection. *See* pp. 12–14, *supra*. To be sure, the Act's application to patented drugs would trigger preemption even without that specific targeting. *See Saleh v. Titan Corp.,* 580 F.3d 1, 12 n.8 (D.C. Cir.

2009) ("[I]t is a black-letter principle of preemption law that generally applicable state laws may conflict with and frustrate the purposes of a federal scheme just as much as a targeted state law."); *United States v. California*, 921 F.3d 865, 880 (9th Cir. 2019) ("Obstacle preemption … attaches to any state law, regardless of whether it specifically targets the federal government."). But the Board's focus on patent rights as an important factor justifying the imposition of state price controls makes the Act's interference with federal objectives even clearer.

The Board cannot deny that Amgen's patents were a major, if not the most significant, factor in the decision to subject Enbrel to price controls. Its Chair stated on the record that the Board "decided not to do an affordability review" for a therapeutic alternative that was historically more expensive than Enbrel because that product, unlike Enbrel, had recently become subject to biosimilar competition. *See* p. 14, *supra*. And the Board's affordability report emphasized Amgen's patent rights and their role in limiting biosimilar competition. It included a detailed overview of relevant patents, observing that "Enbrel has patent protection and is protected from biosimilar competition" by patents that will not expire until 2029. Compl. Ex. D at 25; *see id.* at C-11–C-13. It also drew a contrast with "[t]wo of Enbrel's therapeutic alternatives," noting that they "have recent FDA-approved biosimilar products." *Id.* at 25. The Board stated it found consideration of Amgen's patents "helpful" because "intellectual property rights can be associated with increased drug prices." *Id.* at C-11.

Given the Board's close scrutiny of Enbrel's patents, there can be little doubt that the rights guaranteed by the federal patent laws were a key factor in the Board's decision. The Board was open about its desire to use state law to counteract the effect of Amgen's federal patent rights on the price of Enbrel. Although such explicit targeting of federally protected rights is not necessary for preemption, it confirms that Colorado's price-control regime "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of" the federal patent laws. *Crosby*, 530 U.S. at 373 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

II. Colorado's price-control regime lacks meaningful standards and thus violates due process.

Colorado's delegation of virtually unfettered price-setting power to the Board is also unconstitutional because it lacks the procedural safeguards necessary to comport with basic requirements of due process. The Due Process Clause prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. Amgen has a protected property interest in Enbrel. And it is "well-settled" that "the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself" and "within the protection of" due process. *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936). Yet neither Colorado's statute nor the implementing regulations establish any standard to constrain the Board's discretion either in determining whether a drug is "unaffordable" or in setting an "upper payment limit." This lack of ascertainable standards violates due process by denying manufacturers

a meaningful opportunity to be heard and failing to protect them against arbitrary, confiscatory, or discriminatory deprivations.

1. "The core of due process is the right to notice and a *meaningful opportunity* to be heard." *In re C.W. Mining Co.*, 625 F.3d 1240, 1244–45 (10th Cir. 2010) (quoting *LaChance v. Erickson*, 522 U.S. 262, 266 (1998)); *see Mathews v. Eldridge,* 424 U.S. 319, 333 (1976). For a hearing to be meaningful, the law must set "ascertainable limit[s]" on the agency's discretion. *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1185–86 (10th Cir. 2009); *see White v. Roughton*, 530 F.2d 750, 753–54 (7th Cir. 1976) (per curiam) ("The requirements of due process include a determination of the issues according to articulated standards."). "[U]ncontrolled discretion in an agency of government" is "an intolerable invitation to abuse." *Hobbs*, 579 F.3d at 1185 (quoting *Holmes v. N.Y. City Hous. Auth.*, 398 F.2d 262, 264–65 (2d Cir. 1968)). The purpose of due process is to prevent "erroneous deprivation[s]," *Eldridge*, 424 U.S. at 335; but without meaningful standards, there is no yardstick to measure whether a decision is erroneous and no way to hold the agency accountable. "The lack of such standards … deprives any hearing, whether before an agency or a court, of its meaning and value." *White*, 530 F.2d at 754.

Colorado's price-control regime violates due process because the Board's decisionmaking is not governed by any ascertainable standards. The central question the Board must answer is whether a given drug is "unaffordable for Colorado consumers." Yet the statute does not define that term or meaningfully limit the

Board's discretion to deem particular drugs "unaffordable." The Board need only "consider" a multitude of factors "to the extent practicable," and it can name "any other factors" it wants in regulations. Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E). Most of the factors are extraordinarily broad and vague, and neither the statute nor the regulations explain how to assess or weigh those factors. *See* pp. 8–9, *supra*. As a result, the Board's decisionmaking is effectively a black box—as illustrated by the Board's determination that Enbrel, with an average annual per-patient cost of $46,772 and average annual out-of-pocket cost of $3,980, is unaffordable, while Trikafta, an "extraordinarily expensive drug" with an average annual per-patient cost of $234,439 and average annual out-of-pocket cost of nearly $9,000, is not unaffordable.[9] The Board's reports on Trikafta and Enbrel total more than 1,000 pages, yet a reader of those reports can only guess about what specific considerations caused the Board to deem Enbrel unaffordable and Trikafta affordable. At the end of the day, the Board is left to its own "uncontrolled discretion." *Hobbs*, 579 F.3d at 1185.

The Board's discretion in setting an "upper payment limit" for a drug it has deemed unaffordable is similarly standardless. The statute does not impose any meaningful constraint on the Board's power to dictate prices—there is no price floor, nor even any standard of reasonableness or fairness. Colo. Rev. Stat. § 10-16-1407(2).

[9] *Compare* Compl. Ex. D at 2 *with* Colo. PDAB, 2023 Affordability Review Report: Trikafta, at 2–3 (Dec. 15, 2023), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board.

The Board is required only to "consider" or "review" certain factors before choosing a price—but how those factors should affect the Board's decision, if at all, is left unsaid. *See* pp. 9–10, *supra*. Accordingly, at both stages of the administrative process, regulated parties and other stakeholders are subject to the whims of the Board. This scheme violates Amgen's "due process right to be free from" determinations unconstrained by "any publicly-available standard." *Hobbs*, 579 F.3d at 1185.

2. Colorado's regime also violates the more specific due-process principles that courts have applied to administrative price-control regimes. Government price-setting is a potent form of economic regulation that can impose severe burdens on private rights, which in turn can undermine the public interest by creating shortages and reducing incentives for production and innovation. Courts thus have long held that a statute that authorizes an agency to set prices must contain both substantive standards and procedural mechanisms sufficient to "ensure a fair and reasonable rate of return on investment." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 594 (6th Cir. 2001); *see also Guaranty Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990).

A constitutional price must not only allow the seller to recoup its costs; it must also include "compensat[ion] … for the risk assumed." *Mich. Bell*, 257 F.3d at 593 (quoting *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 603 (1944)); *see Tenoco Oil Co. v. Dep't of Consumer Affairs*, 876 F.2d 1013, 1020 (1st Cir. 1989) (rates that do not allow a "fair return on investment" are "confiscatory"). It is not enough that an agency might happen to select a constitutional price; instead, the price-setting

regime must include standards and procedures to *ensure* a constitutionally reasonable price. The Sixth Circuit thus struck down a state law regulating telephone rates because the statute's standards and factors "d[id] not guarantee the constitutionally-required fair and reasonable rate of return." *Mich. Bell*, 257 F.3d at 595–96. The Ninth Circuit likewise invalidated a state law regulating insurance rates because it did not "provide[] any mechanism to guarantee a constitutionally required fair and reasonable return." *Guaranty*, 916 F.2d at 512–15.

Colorado's price-control scheme fails to provide these minimum constitutional safeguards. Neither the statute nor the regulations require that prices set by the Board be sufficient to allow a fair and reasonable return on drug manufacturers' investments. In fact, a fair rate of return is not even listed among the many factors the Board is required to consider when determining whether a drug is "unaffordable" and fixing an upper payment limit. The possibility that the Board might, by chance, set prices at a constitutional level does not satisfy due process. As the Sixth Circuit explained, "it is axiomatic that due process guarantees a fair and reasonable regulatory rate, not just the possibility of acquiring such a rate" through the price-setting authority's discretionary choice. *Mich. Bell*, 257 F.3d at 595 n.4. Far from safeguarding against unconstitutional prices, Colorado's scheme practically invites them by failing to provide any meaningful standards to limit the Board's discretion. Because the Act lacks "any mechanism to guarantee a constitutionally required fair and reasonable return," it violates due process. *Guaranty*, 916 F.2d at 512; *accord*

Mich. Bell, 257 F.3d at 595–96.

III. Colorado's attempt to regulate prices paid by federal healthcare programs is preempted.

Colorado's statute is also preempted insofar as it purports to dictate the prices that federal healthcare programs can pay for Enbrel and other prescription drugs on behalf of program beneficiaries. Under the Act, an "upper payment limit" applies to "*any* financial transaction concerning the purchase of or reimbursement for the prescription drug." Colo. Rev. Stat. § 10-16-1401(23) (emphasis added). There is no exemption for transactions entered into by federal programs such as Medicare, TRICARE, the Veterans Health Administration ("VHA"), and the Federal Employee Health Benefits Program ("FEHB"). Colorado's attempt to govern those federal transactions is preempted under basic constitutional principles prohibiting state regulation of federal activities, as well as under express statutory preemption clauses applicable to certain federal healthcare programs.

1. A basic tenet of our federal system is that the Supremacy Clause "prohibit[s] States from interfering with or controlling the operations of the Federal Government." *United States v. Washington*, 596 U.S. 832, 838 (2022) (citing *McCulloch v. Maryland*, 17 U.S. 316 (1819)). As the Supreme Court has explained, it is "the very essence of supremacy to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments, as to exempt its own operations from their own influence." *Hancock v. Train*, 426 U.S. 167, 178 (1976) (quoting *McCulloch*, 17 U.S. at 427). In other words, "the activities of the

Federal Government are free from regulation by any state." *Id.* (quoting *Mayo v. United States*, 319 U.S. 441, 445 (1943)); *see United States v. Sup. Ct. of N.M.*, 839 F.3d 888, 927 (10th Cir. 2016) (noting "the fundamental importance of the principles shielding federal installations and *activities* from regulation by the States" (quoting *Hancock*, 426 U.S. at 179)).

Colorado violates this principle by seeking to directly regulate the prices that federal healthcare programs pay for Enbrel and other drugs. These programs routinely enter into contracts to purchase or reimburse the purchase of prescription drugs for beneficiaries. Yet under the Act, "[a]n upper payment limit applies to *all* purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state," including purchases and reimbursements by federal healthcare programs. Colo. Rev. Stat. § 10-16-1407(5) (emphasis added). Colorado thus subjects federal programs "to the discretionary authority of a state agency for the terms on which [they] can make arrangements for" the purchase of prescription drugs. *Pub. Utils. Comm'n v. United States*, 355 U.S. 534, 539 (1958). That scheme interferes with the operations of the federal government, which is entitled to control its own payment and coverage decisions "free from regulation by any state." *Mayo*, 319 U.S. at 445. The Act's failure to "exempt [those] operations from [its] influence," *Hancock*, 426 U.S. at 178–79 (quoting *McCulloch*, 17 U.S. at 427), violates the Supremacy Clause.

Perhaps recognizing this problem, in January 2023, the Board issued a non-

binding policy document asserting, without explanation, that "[a]n upper payment limit does not apply to [a] purchase or reimbursement made by Medicare." Compl. Ex. A at 2. That policy document does not solve the constitutional problem. For one thing, it refers only to Medicare and does not address other federal healthcare programs. And even as to Medicare, the Board's assertion is contrary to the plain language of the statute and does not purport to be binding on anyone. It therefore does not provide adequate assurance against preempted applications of the statute.

2. Colorado's attempt to dictate the prices federal healthcare programs can pay for prescription drugs is also preempted under express preemption provisions applicable to several of those federal programs. Start with Medicare. As the Tenth Circuit has recognized, the Medicare Part C and D programs have "broad preemption clause[s]." *Pharm. Care Mgmt. Ass'n v. Mulready* ("*PCMA*"), 78 F.4th 1183, 1205 (10th Cir. 2023). The clauses provide that any "standards established under [Part C or D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to" Part C or D plans. 42 U.S.C. § 1395w-26(b)(3) (Part C); *see id.* § 1395w-112(g) (Part D). This "sweeping" language "is 'akin to field preemption' and precludes States from regulating Part [C or] D plans except for licensing and plan solvency." *PCMA*, 78 F.4th at 1206. Colorado's price-control scheme regulates Part C or D plans, does not pertain to licensing or plan solvency, and is therefore expressly preempted.

Colorado's scheme is likewise preempted under broad preemption clauses

applicable to other federal healthcare programs. The statutes and regulations governing TRICARE, a health benefit program for members of the U.S. armed forces, shield TRICARE from the application of state laws "relating to health insurance, prepaid health plans, or other health care delivery or financing methods." 10 U.S.C. § 1103; *see* 32 C.F.R. §§ 199.17(a)(7), 199.21(o)(2). Similarly, the FEHB's express preemption clause provides that "[t]he terms of any contract under this chapter which relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans." 5 U.S.C. § 8902(m)(1). Even a "general" state law "relates to health insurance" when its "*application* relates to the scope or administration of federal healthcare plans." *Gonzalez v. Blue Cross Blue Shield Ass'n*, 62 F.4th 891, 903–04 (5th Cir. 2023). Accordingly, Colorado's attempt to dictate the prices TRICARE and FEHB plans can pay for prescription drugs is expressly preempted.

IV. Colorado's direct regulation of out-of-state transactions violates the Commerce Clause.

The Act's expansive scope causes it to run afoul of another constitutional prohibition: the rule that a state cannot directly regulate transactions that occur entirely outside its borders. This extraterritoriality principle is inferred from the Constitution's Commerce Clause, which grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. As the Supreme Court has long recognized, that affirmative grant of power to Congress implies "a further, negative

command, one effectively forbidding the enforcement of certain state economic regulations even when Congress has failed to legislate on the subject." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (cleaned up).

Under the Commerce Clause, a state law "that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid" per se. *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989); *see Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 668 (4th Cir. 2018) ("A state law violates the extraterritoriality principle if it … expressly applies to out-of-state commerce."). And "[t]he mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions." *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615 (9th Cir. 2018); *see Edgar v. MITE Corp.*, 457 U.S. 624, 642–43 (1982) (plurality opinion) ("The Commerce Clause also precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State.").

The Act violates that extraterritoriality principle because it directly regulates transactions that occur entirely outside of Colorado. An upper payment limit set by the Board "applies to *all* purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state." Colo. Rev. Stat. § 10-16-1407(5) (emphasis added); *see also id.* § 10-16-1401(23) (upper payment limit applies to "*any* financial transaction concerning the purchase of or reimbursement for the prescription drug" (emphasis added)). The upper payment limit thus applies to

"upstream" transactions—transactions that occur entirely outside of Colorado but involve a drug later dispensed or administered in Colorado (*e.g.*, a sale by a manufacturer in Ohio to a distributor in Illinois). The Commerce Clause does not permit Colorado to dictate prices for those out-of-state transactions.

The Fourth Circuit applied these principles to strike down a similar effort by Maryland to "control[] the price of transactions that occur[red] wholly outside the state." *Ass'n for Accessible Meds.*, 887 F.3d at 671. In that case, Maryland prohibited so-called "price gouging in the sale of an essential off-patent or generic drug." *Id.* (quoting Md. Code Ann., Health-Gen. § 2-802(a)). Although the only drugs subject to the law were those that were ultimately "'made available for sale in [Maryland],'" the court held that the law was "nonetheless invalid because it still control[led] the price of transactions that occur[red] wholly outside the state," *id.* at 671. Maryland's attempt to directly regulate prices in out-of-state transactions was a clear constitutional violation, and "[a]ny legitimate effects the Act may have [had] in Maryland [were] insufficient to protect the law from invalidation." *Id.* at 672.

For the same reasons, a federal district court recently held that a similar Minnesota law violated the Commerce Clause. *Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586 (D. Minn. Dec. 4, 2023), *appeal filed*, No. 24-1019 (8th Cir. Jan. 3, 2024). The law prohibited any "excessive price increase" in "the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state." *Id.* at *1

(quoting Minn. Stat. § 62J.842).[10] While the statute required "some nexus" with Minnesota, *Daniels*, 889 F.3d at 615, it reached transactions that occurred completely outside the state's borders. As the court explained, a state may not "directly regulate a sale that occurs in another state simply because the product eventually makes its way into [the state]." *Ass'n for Accessible Meds.*, 2023 WL 8374586, at *3. The same principle applies here. Colorado may not directly regulate out-of-state transactions simply because the drugs involved are ultimately dispensed or distributed in-state.[11]

Moreover, even if Colorado's attempt to directly regulate out-of-state transactions were not invalid per se, it would violate the Commerce Clause under the *Pike* balancing test, which asks whether a state law imposes a burden on interstate commerce that "is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *see Ass'n for Accessible Meds.*, 2023 WL 8374586, at *9. Because Colorado has no legitimate interest in directly regulating transactions that occur entirely outside its boundaries, and because any cognizable local benefits could be achieved by regulating in-state transactions, Colorado's

[10] The Maryland and Minnesota price-control laws in these cases were limited to off-patent or generic drugs. Unlike Colorado, those states did not seek to regulate the price of *patented* drugs, presumably because they recognized that any attempt to do so would impermissibly conflict with the federal patent laws. *See* Part I, *supra*.

[11] As the Minnesota district court and others have recognized, the Supreme Court's decision in *Pork Producers* "did not change the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it." *Ass'n for Accessible Meds*, 2023 WL 8374586, at *3; *see also, e.g.*, *Interlink Prod. Int'l, Inc. v. Crowfoot*, 678 F. Supp. 3d 1216, 1223 (E.D. Cal. 2023).

attempt to regulate extraterritorially fails the *Pike* balancing test.

V. This case presents a justiciable controversy, and the Court should exercise jurisdiction.

Given the strength of Amgen's constitutional claims, Defendants may seek to delay this Court's review by raising unfounded justiciability arguments. Defendants' answer lists several "affirmative defenses," including that Amgen "do[es] not have standing," that its claims are "not justiciable," "not ripe," or "moot," and that "[t]he Court should abstain from hearing this suit under the *Burford* doctrine." ECF No. 23 at 45. It is not clear which, if any, of those arguments Defendants intend to raise in their briefing, but they are all meritless. This case presents a justiciable controversy and does not meet the stringent requirements for *Burford* abstention.

1. With respect to justiciability, "courts have consistently found a case or controversy in suits between state officials charged with enforcing a law and private parties potentially subject to enforcement." *Consumer Data Indus. Ass'n v. King*, 678 F.3d 898, 905 (10th Cir. 2012). In a pre-enforcement challenge to a statute, Article III requires (1) a "threatened injury" that is "certainly impending" or has a "substantial risk" of occurring; (2) a "causal connection" between the injury and the statute; and (3) a "likelihood" that the injury "will be redressed by a favorable decision." *Susan B. Anthony List v. Driehaus ("SBA")*, 573 U.S. 149, 158 (2014) (cleaned up); *see Kane County v. United States*, 928 F.3d 877, 888 (10th Cir. 2019). In short, "[a] plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *BIO,* 496 F.3d at 1370–

71 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). "In pre-enforcement challenges, moreover, standing and ripeness often 'boil down to the same question.'" *Teva Pharms., USA, Inc. v. Weiser*, 2023 WL 9425674, at *5 (D. Colo. Dec. 27, 2023) (quoting *SBA*, 573 U.S. at 157 n.5), *appeal filed*, No. 24-1035 (10th Cir. Jan. 29, 2024).

Amgen faces far more than a "substantial risk" or a "realistic danger" of injury from the Act's operation or enforcement. The Act's express purpose is to reduce what state officials consider "excessive" prescription drug prices, and the Board's *raison d'être* is to effectuate that purpose by imposing "upper payment limits" on drugs the Board deems unaffordable. Colo. Rev. Stat. § 10-16-1403(1). The Board has already engaged in a months-long review of Enbrel that culminated in a 534-page report and two formal votes: one to declare Enbrel "unaffordable for Colorado consumers," and another to "select Enbrel for establishment of an upper payment limit." All that remains to be decided in this autumn's rulemaking is *how much* Enbrel's price will be limited. *See* 3 Colo. Code Regs. § 702-9:4.1(D). And even in the unlikely event that the price reduction is small, "a loss of even a small amount of money" is sufficient to establish standing. *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017). Amgen does "not have to await the consummation of [that] threatened injury to obtain preventive relief." *BIO*, 496 F.3d at 1370–71 (quoting *Babbitt*, 442 U.S. at 298).

Nor does it matter that the Board could, in theory, reconsider its decision to impose an upper payment limit for Enbrel and not complete the rulemaking. There

is no reason to think that, after all the time and resources the Board has invested in declaring Enbrel "unaffordable" and voting to subject it to an upper payment limit, the Board will suddenly change its mind. As the D.C. Circuit has observed, "an agency *always* retains the power to revise" its decisions, so "[i]f the possibility of unforeseen amendments were sufficient to render an otherwise fit challenge unripe, review could be deferred indefinitely." *Am. Petroleum Inst. v. EPA*, 906 F.2d 729, 739–40 (D.C. Cir. 1990) (per curiam). For that reason, "any agency attempt to defeat review by the bare assertion that the agency position may some day change should be summarily rejected." 13B Wright & Miller, Federal Practice and Procedure § 3532.6 (3d ed.); *see, e.g.*, *sPower Dev. Co. v. Colo. Pub. Utils. Comm'n*, 2018 WL 4368612, at *7 (D. Colo. June 18, 2018) (concluding that challenge to agency action was ripe because agency had not "committed to revising or rescinding" challenged rule but had only stated that rulemaking "'may serve as an opportunity to reexamine [its] policies'"). Here, likewise, the theoretical possibility that the Board could reconsider its decision to impose an upper payment limit on Enbrel does not render this challenge unripe.

Moreover, in addition to the threat of injury from imposition of an upper payment limit, Amgen is already suffering (and will continue to suffer) concrete harm as a result of the Board's unconstitutional proceedings. Amgen is being forced to incur substantial costs to participate and defend its interests in a state price-setting process that is preempted and lacks essential due process protections. Amgen's challenge to this process is ripe because "the process itself is preempted … regardless of what the

outcome" might be, and "focus[ing] on the possible ultimate result of the state regulatory process" overlooks that the "process itself can be the preempted burden." *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 342–44 (3d Cir. 2001); *see also, e.g.*, *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 453–54 (9th Cir. 1993) (preemption challenge to state permitting process was ripe because "[t]he hardship is the process itself," which "may impose cost and uncertainty"); *Middle S. Energy, Inc. v. Ark. Pub. Serv. Comm'n*, 772 F.2d 404, 413 (8th Cir. 1985) (similar); *sPower*, 2018 WL 4368612, at *7 (where plaintiff challenges state process as preempted, "[t]he outcome of that process … does not dictate whether [the] claim is ripe" (cleaned up)). Similarly, "a procedural due process claim is instantly cognizable in federal court without requiring a final decision … from the responsible … agency" because "the allegedly infirm process is an injury in itself." *Nasierowski Bros. Inv. Co. v. City of Sterling Heights*, 949 F.2d 890, 894 (6th Cir. 1991) (cleaned up).

Nothing that happens in the Enbrel rulemaking hearings scheduled for later this year will change any facts relevant to Amgen's claims, which raise "strictly legal issues." *United States v. Ford*, 882 F.3d 1279, 1283–84 (10th Cir. 2018). "A purely legal claim in the context of a facial challenge is presumptively reviewable." *Sanchez v. Off. of State Superintendent of Educ.*, 959 F.3d 1121, 1124 (D.C. Cir. 2020) (cleaned up). The purely legal nature of Amgen's claims means that "waiting for [the rulemaking hearings] to play out" would not "significantly advance [this Court's] ability to deal with the legal issues presented or aid [it] in their resolution." *Sup. Ct.*

of N.M., 839 F.3d at 903–04 (cleaned up). And it would make no sense to force Amgen to incur the costs of an unconstitutional process before challenging that process as unconstitutional. This case is ripe for review now.[12]

2. Defendants' answer also indicates that they may invoke *Burford* abstention, but that doctrine has no application here. Given the "strong federal interest" in having federal rights "adjudicated in federal court," *Burford* abstention is "rare[]" and "represents an 'extraordinary and narrow exception to the duty of the District Court to adjudicate a controversy properly before it.'" *Quackenbush v. Allstate Ins. Co.*, 517 U.S. 706, 728 (1996) (quoting *Colo. River Water Conservation Dist. v. United States*, 424 U.S. 800, 813 (1976)). The Supreme Court has limited *Burford* abstention "to situations where 'there are difficult questions of state law bearing on policy problems … whose importance transcends the result in the case' or 'where the exercise of federal review of the question in a case and in similar cases would be disruptive of state efforts to establish a coherent policy with respect to a matter of substantial public concern.'" *Tavernier v. Colo. State Bd. of Nursing*, 2017 WL 1242995, at *14 (D. Colo. Mar. 17, 2017) (quoting *Oklahoma ex rel. Doak v. Acrisure Bus. Outsourcing Servs., LLC*, 529 F. App'x 886, 897 (10th Cir. 2013)).

This case does not present the "narrow range of circumstances in which *Burford* can justify the dismissal of a federal action." *Quackenbush*, 517 U.S. at 726–

[12] Meanwhile, the Board continues to move forward with proceedings targeting other drugs. Declining to reach the merits now would only mean that Amgen or another affected company would bring the same challenge in a few months.

28. Amgen's "claims both are federal in nature and do not implicate any difficult questions of state law." *Tavernier*, 2017 WL 1242995, at *14 (cleaned up). Nor would Amgen's challenge "disrupt the State's attempt to ensure uniformity in the treatment of an essentially local problem." *Quackenbush*, 517 U.S. at 727 (cleaned up). Notably, "[w]hile *Burford* is concerned with protecting complex state administrative processes from undue federal influence, it does not require abstention whenever there exists such a process, or even in all cases where there is a 'potential for conflict' with state regulatory law or policy." *Id.* For example, "*Burford* abstention is inappropriate where, like here, the plaintiff asserts a well-founded preemption claim." *sPower*, 2018 WL 4368612, at *9–10 (adopting then-Magistrate Judge Wang's recommendation to reject *Burford* abstention); *see Quackenbush*, 517 U.S. at 727 (noting that "federal adjudication" of preemption claim "would not disrupt the State's attempt to ensure uniformity in the treatment of an essentially local problem" (cleaned up)). Preemption is "a pure federal-law question." *Allison v. UNUM Life Ins. Co.*, 381 F.3d 1015, 1027 n.1 (10th Cir. 2004) (cleaned up). The Board can only benefit from knowing, as early as possible, whether and to what extent Colorado's price-control scheme is preempted. *Cf. sPower*, 2018 WL 4368612, at *10 ("[C]lear guidance from this Court on [federal preemption] may actually accelerate and add to [the state agency's] efforts"). For all these reasons, *Burford* abstention is clearly unwarranted.

CONCLUSION

The Court should enter summary judgment in Amgen's favor.

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Respectfully submitted,

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