UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

AMGEN INC.;
IMMUNEX CORPORATION; and
AMGEN MANUFACTURING LIMITED LLC,

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board;
SAMI DIAB, MD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
AMARYLIS GUTIERREZ, PharmD, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
CATHERINE HARSHBARGER, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
JAMES JUSTIN VANDENBERG, PharmD, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board;
MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance; and
PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,

Defendants.

Civil Action

No. 1:25-cv-3452

COMPLAINT

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PRELIMINARY STATEMENT

1. Innovative drugs have enriched the lives of countless Coloradans. One of those drugs, Amgen's patented drug ENBREL®, provides disease-transforming and life-changing relief every year to more than 3,000 Coloradans who suffer from arthritis and other autoimmune diseases. As one example, Enbrel effectively redefined the clinical course of moderate to severe rheumatoid arthritis, allowing many patients who previously would have endured progressive and painful deformities and immobility to live with less pain, slower progression, and greater function.

2. Often, innovative drugs like Enbrel are available at very little out-of-pocket cost to the patient. But in February 2024, Colorado's newly created "Prescription Drug Affordability Review Board," ignoring the concerns of patient-advocacy groups, unlawfully found Enbrel to be "unaffordable"—a term not defined in any statute or regulation—and voted to subject Enbrel to a price cap known as an "upper payment limit" ("UPL"). Then, after a series of hearings, the Board unlawfully adopted a final rule on October 3, 2025, fixing the price cap for Enbrel at a fraction of Enbrel's market price. The rule will take effect on January 1, 2027.

3. The Board's actions, and the statutory scheme on which they are based, are unconstitutional because they conflict with federal patent law,

violate basic requirements of due process, and impermissibly seek to regulate conduct occurring outside of Colorado. In flouting the Constitution and federal law, the Board's actions jeopardize access to Enbrel and other innovative drugs, endangering the lives and well-being of countless patients with serious medical conditions.

4. Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing Limited LLC (collectively, "Amgen") bring this action for declaratory and injunctive relief against the Board Chair and other members of the Board in their official capacities, the Commissioner of the Colorado Division of Insurance in his official capacity, and the Attorney General of the State of Colorado in his official capacity (collectively, "Defendants"), alleging as follows:

NATURE OF THE ACTION

5. This lawsuit seeks to have the Court declare invalid, and enjoin the enforcement of, a Colorado law that unconstitutionally delegates sweeping authority to a new "Prescription Drug Affordability Review Board" to impose arbitrary price controls on the sale of prescription drugs, including drugs protected by the federal patent laws. *See* Colo. Rev. Stat. § 10-16-1401 *et seq.*

6. Enacted as Senate Bill 21-175, and amended by House Bill 23-1225, the stated purpose of Colorado's price-control statute ("the Act") is to

"protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1). The Act seeks to accomplish that goal in ways that violate the Constitution, conflict with federal law, and threaten patient access to lifesaving medical innovations.

7. The Act provides that the Prescription Drug Affordability Review Board "shall … [c]ollect and evaluate information concerning the cost of prescription drugs sold to Colorado consumers," "[p]erform affordability reviews of prescription drugs," and "[e]stablish upper payment limits for prescription drugs." *Id.*

8. The Act confers vast unguided discretion on the Board to declare certain prescription drugs "unaffordable for Colorado consumers." *Id.* § 10-16-1406. If the Board deems a prescription drug to be "unaffordable for Colorado consumers," the Board is empowered to impose an "upper payment limit" on the drug, which applies to "all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by other means." *Id.* § 10-16-1407. The Act does not provide any standards, definitions, or guidance to constrain the Board's decisions about what it means for a drug to be "unaffordable" or what the "upper payment limit" for a drug should be.

9. The Act does not contain any exemption for prescription drugs that

are patented under federal law, and the Board has stated that it is targeting drugs, like Enbrel, that are protected by the federal patent laws because patents limit competition. Restricting competition during a defined period of market exclusivity is, of course, a deliberate element of federal law. The Constitution's Patent and Copyright Clause expressly vests in Congress the power to encourage innovation and creativity by protecting intellectual property rights. U.S. Const. art I, § 8, cl. 8. Patents reward inventors with the ability, for a limited time, to charge prices that can be used to help fund further important investment and facilitate additional innovation during and beyond the term of the patent.

10. The Board's novel regulatory scheme and its imposition of an upper payment limit on Enbrel violate the U.S. Constitution in at least three ways.

11. *First*, the Act violates the Supremacy Clause because it conflicts with the federal patent laws, including the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"). To incentivize the immense risk-taking and investment necessary to discover and develop new medical treatments, Congress has established a carefully calibrated intellectual property regime that rewards pharmaceutical innovation with a period of market exclusivity and the ability to charge prices

that allow for further investment and innovation during that period. The Act upsets that federal legislative balance by allowing five members of a state-created board to strip away the rights and economic incentives that Congress sought to create in enacting the patent laws.

12. *Second*, the Act violates the Due Process Clause of the Fourteenth Amendment because it lacks the procedural protections necessary to guide the Board's decision-making and avoid the imposition of arbitrary, confiscatory, or otherwise constitutionally inappropriate prices. Neither the Act nor the Board's implementing regulations provide any standard for the Board to apply either when determining whether a drug is "unaffordable" or when setting an "upper payment limit" (nor has the Board even adopted such standards through individualized adjudication with respect to specific drugs). As a result, the Act fails to provide drug manufacturers with a meaningful opportunity to be heard and fails to protect them against erroneous deprivations of their property.

13. *Third*, the Act violates the Commerce Clause because it purports to regulate commercial transactions that occur entirely outside the state of Colorado, merely because the drugs involved in those transactions later make their way into Colorado.

14. For these reasons, and as further explained below, this Court

should declare the Act unconstitutional and enjoin its enforcement as to Enbrel.

PARTIES

15. Plaintiff Amgen Inc. is a biopharmaceutical company that discovers, develops, manufactures, and delivers innovative medicines to fight some of the world's toughest diseases. Amgen Inc. focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that dramatically improve people's lives, while also reducing the social and economic burden of disease. Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

16. Plaintiff Immunex Corporation ("Immunex") is a wholly owned subsidiary of Amgen Inc. and the manufacturer of the patent-protected drug Enbrel, an injectable medicine that is approved for the treatment of a variety of autoimmune diseases such as moderate to severe rheumatoid arthritis, psoriatic arthritis, and moderate to severe plaque psoriasis. Immunex is a corporation organized and existing under the laws of the State of Washington with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

17. Plaintiff Amgen Manufacturing Limited LLC ("AML") is an

indirect wholly owned subsidiary of Amgen Inc. Since its inception, AML has invested billions of dollars to provide a reliable and safe source of drug supply for patients. To this end, AML has been involved in the complex manufacturing of Enbrel drug substance from living cells and then transforming the active medicine into drug product that can be administered to patients. AML helps to ensure top-quality operations and innovative enhancements to the manufacturing process. AML is a Puerto Rico limited liability company, with its principal place of business at Carr. 31, Km 24.6, Juncos, Puerto Rico 00777.

18. Defendant Gail Mizner, MD, FACP, AAHIVS, of Snowmass Village, Colorado, is sued in her official capacity as the Chair of the Prescription Drug Affordability Review Board.

19. Defendant Sami Diab, MD, of Greenwood Village, Colorado, is sued in his official capacity as a member of the Prescription Drug Affordability Review Board.

20. Defendant Amarylis Gutierrez, PharmD, of Aurora, Colorado, is sued in her official capacity as a member of the Prescription Drug Affordability Review Board.

21. Defendant Catherine Harshbarger, of Holyoke, Colorado, is sued in her official capacity as a member of the Prescription Drug Affordability Review Board.

22. Defendant James Justin VandenBerg, PharmD, BCPS, of Denver, Colorado, is sued in his official capacity as a member of the Prescription Drug Affordability Review Board.

23. Defendant Michael Conway is sued in his official capacity as the Commissioner of the Colorado Division of Insurance, which oversees the Prescription Drug Affordability Review Board. *See* Colo. Rev. Stat. §§ 10-16-1402(1), 24-1-105(1)(b). If a manufacturer of a prescription drug subject to an upper payment limit seeks to withdraw its drug from sale or distribution in Colorado, the manufacturer must provide written notice to the Commissioner at least 180 days prior to the withdrawal. *Id.* § 10-16-1412(1)(a). The Commissioner may impose a penalty of up to $500,000 if the manufacturer fails to provide the requisite notice. *Id.* § 10-16-1412(3). Commissioner Conway maintains an office in Denver, Colorado.

24. Defendant Philip Weiser is sued in his official capacity as the Attorney General of the State of Colorado. The Attorney General is "authorized to enforce [the Act] on behalf of any state entity or any consumer of prescription drugs." *Id.* § 10-16-1411(3). Attorney General Weiser maintains an office in Denver, Colorado.

JURISDICTION AND VENUE

25. This Court has original subject matter jurisdiction over this case

pursuant to 28 U.S.C. § 1331 because it arises under the Constitution and laws of the United States.

26. This Court has personal jurisdiction over Defendants because they are domiciled in Colorado, because the enactment of the state laws at issue in this lawsuit occurred within Colorado, and because the implementation of those laws has occurred and will continue to occur within the state.

27. An actual controversy exists between the parties with respect to the validity and enforceability of the Colorado laws at issue, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202, 42 U.S.C. § 1983, Federal Rules of Civil Procedure 57 and 65, and this Court's inherent equitable powers.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(1) because at least one Defendant resides in this District and all Defendants are residents of the State in which this District is located. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in this District.

STATUTORY AND REGULATORY BACKGROUND

The Federal Patent System

29. 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. As the Supreme Court has explained, "[t]he economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors." *Mazer v. Stein*, 347 U.S. 201, 219 (1954). American intellectual property law thus "*celebrates* the profit motive" because it "recogniz[es] that the incentive to profit … will redound to the public benefit by resulting in the proliferation of knowledge." *Eldred v. Ashcroft*, 537 U.S. 186, 212 n.18 (2003) (quotation marks omitted).

30. Pursuant to its constitutional power to protect intellectual property and promote technological innovation, Congress has established an extensive, nationally uniform system for the granting and maintenance of patents. *See* 35 U.S.C. § 1 *et seq*. Under 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. 35 U.S.C. § 154. The "economic rewards during the period of exclusivity" provide a critical "incentive for innovation." *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 costs of the product.

31. The federal patent system thus embodies "a careful balance"

between "the need to promote innovation" by allowing innovators to charge appropriate prices during the term of the patent, and the benefits of greater affordability that flow from "imitation" and increased competition after the patent term expires. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Congress has fine-tuned that balance by specifying the duration of patent terms and establishing procedures for the adjustment of those exclusivity periods under certain circumstances. *See* 35 U.S.C. § 154.

32. Patent protection is especially important for promoting pharmaceutical research and development because of the extraordinary costs and high level of uncertainty involved in seeking to discover and develop new drugs, guide them through the lengthy FDA approval process, and bring them to the patients who need them. The average cost of bringing a single new drug to market is commonly estimated to be more than $2 billion,[1] the process takes an average of 10 to 15 years,[2] and only about 1 in 5,000 potential new drugs

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

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

obtains approval and reaches patients.[3]

33. In 1984, recognizing the unique challenges posed by the costly drug-development process, Congress enacted 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, pt. 1, 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 time-consuming, but essential, testing required by the Food and Drug Administration." Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

34. At the same time, once an innovator drug is no longer patent-protected, Congress has sought to promote the benefits of competition by creating an abbreviated pathway for competing products to obtain FDA approval. For chemically synthesized, small-molecule drugs, that abbreviated

[3] 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.

pathway was created by the Hatch-Waxman Act, which allowed generic versions of those drugs to receive FDA approval without the same level of clinical testing required for approval of a new brand-name drug. *See* 21 U.S.C. § 355(j). For more complex "biologic drugs" (large molecules made from living cells), a similar abbreviated pathway for FDA approval of "biosimilars" was created by the Biosimilar Price Competition and Innovation Act of 2009, commonly known as the "BPCIA." *See* 42 U.S.C. § 262(k).

35. Through these statutory enactments, exercising powers expressly granted to it in the Constitution, Congress struck a deliberate balance in the pharmaceutical arena—allowing those who develop innovative new drugs, and who can be expected to invest in new innovations, to benefit from market exclusivity for a specific and defined period while encouraging price competition thereafter.

Colorado's Price-Control Scheme

36. Colorado's Prescription Drug Affordability Review Board consists of five members appointed by the Governor of Colorado and confirmed by the state senate. Colo. Rev. Stat. § 10-16-1402(2). The Board is an entity within the Colorado Division of Insurance. *Id.* § 10-16-1402(1).

37. The Act provides that, "[t]o protect Colorado consumers from excessive prescription drug costs," the Board "shall … [c]ollect and evaluate

information concerning the cost of prescription drugs sold to Colorado consumers," "[p]erform affordability reviews of prescription drugs," and "[e]stablish upper payment limits for prescription drugs." *Id.* § 10-16-1403. An "upper 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).

38. The Board must first identify a list of prescription drugs eligible for an affordability review based on certain cost-related criteria. *Id.* § 10-16-1406(1); 3 Colo. Code Regs. § 702-9:3.1(C). Eligible drugs include "brand-name drug[s] or biological product[s]" as well as biosimilar and generic drugs that meet the applicable criteria. 3 Colo. Code Regs. § 702-9:3.1(C)(2), (D)(1)(b); Colo. Rev. Stat. § 10-16-1406(1). The manufacturer's list price is the *only* factor the Board is allowed to consider to determine which drugs are eligible for affordability reviews. Colo. Rev. Stat. § 10-16-1406(1).

39. 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." *Id.* § 10-16-1406(2); 3 Colo. Code Regs. § 702-9:3.1(D)(2)(d).

40. When the Board conducts an affordability review for a drug, its task is to "determine whether use of the prescription drug … is unaffordable for Colorado consumers." Colo. Rev. Stat. § 10-16-1406(3). In performing the affordability review, the Board is instructed to "consider" "to the extent practicable" various factors, including: cost-related considerations; "[t]he effect of the price on Colorado consumers' access to the prescription drug"; whether the drug has orphan-drug status under federal law; input from patients, caregivers, and experts; information voluntarily submitted by manufacturers or other entities; and "[a]ny other factors as determined by rules promulgated by the [B]oard." *Id.* § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E).

41. The Board has promulgated rules specifying that it will consider additional factors, including "Rebates, Discounts, and Price Concessions"; "Health Equity Factors"; analyses conducted by the Department of Health Care Policy and Financing; information regarding safety-net providers participating in the federal 340B discount program; and "information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions placed on the prescription

drug." 3 Colo. Code Regs. § 702-9:3.1(E).

42. In conducting the affordability review, the Board "may" also "consider any documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including documents and information relating to: (a) Life-cycle management; (b) The average cost of the prescription drug in the state; (c) Market competition and context; (d) Projected revenue; (e) The estimated cost-effectiveness of the prescription drug; and (f) Off-label usage of the prescription drug." Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E)(3)(a).

43. Despite the provisions directing and authorizing the Board to consider certain information, the statute does not include any definition or standards to guide the Board's decision-making or to help the Board determine when a drug should be classified as "unaffordable" under the statute.

44. If the Board determines that a prescription drug is "unaffordable for Colorado consumers," the Board is authorized to establish an "upper payment limit" for that prescription drug. Colo. Rev. Stat. § 10-16-1407(1)(a).

45. The Act directs the Board to "determine by rule the methodology for establishing an upper payment limit for a prescription drug to protect consumers from the excessive cost of prescription drugs and ensure they can access prescription drugs necessary for their health." *Id.* § 10-16-1407(2). The

methodology "must include consideration" of: "(a) The cost of administering or dispensing the prescription drug; (b) The cost of distributing the prescription drug to consumers in the state; (c) The status of the prescription drug on the drug shortage list published by the drug shortage program within the FDA; and (d) Other relevant costs related to the prescription drug." *Id.* The methodology must also consider the impact on "older adults and persons with disabilities," without placing a lower value on their lives because of disability or age, and must allow pharmacies to charge "reasonable fees" for dispensing or delivering drugs that are subject to an upper payment limit. *Id.* §§ 10-16-1407(3), 10-16-1407(4).

46. The Board's rules state that when establishing upper payment limits, the Board "shall review" the factors specified in § 10-16-1407(2). 3 Colo. Code Regs. § 702-9:4.1(C)(2). The rules further state 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). Similarly, the Board's consideration "may include" whether the prescription drug is on the FDA's drug shortage list and, if so, the Board "may consider" factors such as the estimated shortage duration, the shortage reason, therapeutic classification, and "[o]ther related information." *Id.* § 702-9:4.1(C)(2)(b). The Board's rules do not, however, set forth any

defined methodology for determining the amount of an upper payment limit.

47. Regarding the "Process for Establishing Upper Payment Limits," the Board's rules provide that the Board will set upper payment limits "through rulemaking." *Id.* § 702-9:4.1(D). The Board "shall receive stakeholder information" submitted through the rulemaking, "containing information relevant to any of [the] considerations that the Board may take into account in establishing an upper payment limit." *Id.* § 702-9:4.1(C)(2)(f).

GENERAL ALLEGATIONS

Amgen's Patent-Protected Drug Enbrel

48. Enbrel is an innovative medicine used to treat certain autoimmune diseases, including rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, juvenile psoriatic arthritis, and polyarticular juvenile idiopathic arthritis. 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.

49. Enbrel is a biologic drug, meaning that it is made from living cells. The active ingredient in Enbrel is a fusion protein called etanercept. Etanercept works by attaching to a protein in the body called "tumor necrosis factor" (TNF) and thereby inhibiting TNF's inflammatory activity. When a

patient's immune system produces too much TNF, it may lead to inflammation that causes pain, swelling, and joint damage.

50. 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 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 issued on April 24, 2012.

51. Those two patents grant Enbrel market exclusivity and limit competing biosimilar products from entering the market until 2029 at the earliest.

52. Immunex is the exclusive licensee of all commercial rights in the '182 and '522 patents, including all rights to sell Enbrel in the United States. Immunex has also granted AML an exclusive sublicense to the '182 and '522 patents.

53. Federal courts have upheld the validity of Enbrel's patents, including the patents that limit biosimilar competition until 2029. *See, e.g.*, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2623 (2021) (mem.).

Amgen's Distribution of Enbrel

54. Amgen does not sell Enbrel directly to patients, pharmacies, or

healthcare providers. Instead, as is standard practice in the pharmaceutical industry, Amgen sells Enbrel to wholesalers and distributors, who in turn sell the drug to "downstream" purchasers, such as pharmacies and hospitals.

55. The price at which a drug manufacturer, like Amgen, sells a drug to wholesalers is typically referred to as the "manufacturer's list price," "Wholesale Acquisition Cost," or "WAC." The WAC is a national list price that does not reflect any reductions, including any discounts applicable to pharmacies, hospitals, and other entities that purchase drugs from wholesalers.

56. After purchasing the drug from the manufacturer at WAC, wholesalers typically sell the drug to downstream purchasers, such as pharmacies and hospitals, at a price equivalent to or lower than WAC. Wholesalers' slim profit margins come from discounts they obtain from the manufacturer for prompt payment or administrative service fees they charge the manufacturer for managing distribution of its drugs.

57. When a wholesaler is required to provide a downstream purchaser with a discount or other price reduction below WAC, the drug manufacturer typically reimburses the wholesaler for the discount or price reduction by providing the wholesaler with a payment called a "chargeback." Without that reimbursement, the wholesaler would lose money on the sale.

58. Amgen's wholesale and distribution contracts reflect the standard industry practice of paying chargebacks when a wholesaler is required to sell a drug to a downstream purchaser for less than WAC, thereby ensuring that the other entity does not lose money on the sale.

The Board Declares Enbrel Unaffordable and Votes to Select Enbrel for Imposition of an Upper Payment Limit

59. On June 9, 2023, the Board approved the final list of prescription drugs eligible for affordability reviews. The list included 604 drugs that the Board claimed met one or more of the statutory eligibility criteria to be subject to an affordability review.[4]

60. Enbrel was included on the list of eligible drugs based solely on its WAC, which (as noted above) is the price Amgen charges to wholesalers. *See* Colo. Rev. Stat. § 10-16-1406(1).

61. On August 4, 2023, the Board selected from the list of eligible drugs five drugs for affordability reviews. All of the selected drugs were brand-name drugs covered by unexpired patents. Enbrel was one of those drugs.

62. On February 9, 2024, the Board published its draft affordability

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

review summary report for Enbrel. The report expressly discussed Enbrel's patents as a reason for deeming Enbrel "unaffordable" and subjecting it to an upper payment limit.

63. The report observed that "[c]urrently, Enbrel has patent protection and is protected from biosimilar competition" due to "patents that prevent the introduction of biosimilar products" that are set to expire in 2029.[5] The report contrasted this with "[t]wo of Enbrel's therapeutic alternatives, Humira and Remicade, [which] have recent FDA-approved biosimilar products," and noted that "there is evidence that biosimilar entry for TNF inhibitors resulted in increased utilization and price reduction in European markets."[6]

64. Further emphasizing Enbrel's patent protection, the report included an appendix section specifically devoted to the topic of "Patents and Exclusivity."[7] The report catalogued Enbrel's various patents, highlighted two patents that it stated currently "prevent the introduction of biosimilar products," and 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

[5] Ex. C at 26.

[6] *Id.*

[7] *Id.* at C-9 to C-11.

prices, delayed availability, and increased costs to consumers and governments."[8] The report went on to state 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."[9] Finally, 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.[10]

65. On February 16, 2024, the Board held a meeting at which four of its members (Dr. Diab was recused) voted to declare Enbrel "unaffordable for Colorado consumers."[11] At the meeting, one of the members remarked that even though an Enbrel competitor had historically been more expensive than Enbrel—in fact, the competitor had topped the Board's list of the "top 10 highest spend eligible drugs"[12]—the Board did not conduct an affordability review for the competitor because it had recently become subject to biosimilar

[8] *Id.* at C-9.

[9] *Id.* at C-11.

[10] *Id.*

[11] Ex. E at 104–05.

[12] *See* Ex. B.

competition (*i.e.*, its patent exclusivity period had ended).[13]

66. On February 23, 2024, the Board held a meeting at which three of its members (Dr. Diab was again recused and Ms. Harshbarger was absent) voted to adopt the final affordability review summary report for Enbrel.[14] That same day, the Board then took a second vote to select Enbrel for establishment of an upper payment limit and directed its staff to initiate a rulemaking to determine the precise amount of that upper payment limit.[15]

67. The Board's final affordability review summary report for Enbrel was made publicly available on March 21, 2024. In a new section titled "Board Deliberation and Vote Summary," the report noted 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."[16] The final report was otherwise identical to the draft report in all relevant respects, including the discussion of Enbrel's patents.[17]

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[13] Ex. E at 33–34.

[14] Ex. F at 21–22.

[15] *Id.* at 36–37.

[16] *See* Ex. D at 2–3.

[17] *See id.* at 25 and C-11 to C-13.

Amgen's First Lawsuit
Is Dismissed as Premature

68. On March 22, 2024, after the Board declared Enbrel unaffordable and voted to establish an upper payment limit, Amgen sued the same Defendants that are named here. *See* Complaint, *Amgen Inc. v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 1:24-cv-810 (D. Colo.), Dkt. 1. Amgen pleaded claims based on patent preemption, due process, interference with federal healthcare programs, and the Commerce Clause. *Id.* ¶¶ 66–94.[18]

69. On March 28, 2025, this Court granted defendants' motion for summary judgment as to standing and dismissed Amgen's complaint without prejudice for lack of subject matter jurisdiction. *Amgen Inc. v. Mizner*, 2025 WL 947474 (D. Colo.), *appeal docketed*, No. 25-1641 (Fed. Cir. Apr. 14, 2025).

70. The Court first held that "Amgen is not subject to direct regulation under the Act." *Id.* at *6. In reaching that conclusion, the Court accepted

[18] In response to Amgen's complaint, the Board amended its UPL policy document to state that a UPL "does not apply to the purchase or reimbursement by any federal agency, federal program, Indian Tribe, or non-participating self-funded health benefit plans, including but not limited to, purchases or reimbursements made by Medicare, TRICARE, or the Federal Employee Health Benefits program." Cross-Mot. for Summ. J. at 40–41, *Amgen*, No. 1:24-cv-810 (D. Colo. Aug. 9, 2024), Dkt. 29 (quoting PDAB Policy & Procedures, Pol'y No. 05, Upper Payment Limit Policy and Procedure (July 19, 2024), *available at* https://doi.colorado.gov/sites/doi/files/documents/Adopted%20PDAB%20Policies.pdf). Amgen is thus no longer pursuing a claim for interference with federal healthcare programs.

Defendants' argument that "a UPL does not directly apply to a wholesaler's purchase from a manufacturer" and "applies directly only to downstream transactions," such as "a consumer's purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies and providers' purchases" from wholesalers. *Id.*

71. The Court then held that "Amgen's asserted future injury" from a UPL was "simply too speculative to be 'concrete' and 'imminent.'" *Id.* at *7. The Court emphasized that "no UPL for Enbrel has been set and it is unclear when and if such a UPL will be set." *Id.* at *8. The Court thus reasoned that "[u]nless and until a UPL is set for Enbrel and at a price lower than WAC, … Amgen's alleged future injuries are hypothetical at best." *Id.*

The Board Establishes an Upper Payment Limit for Enbrel

72. On May 23, July 11, August 22, and October 3, 2025, the Board held public rulemaking hearings to establish a price cap for Enbrel. Video recordings of these hearings are available at *PDAB Meetings*, https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board, and transcripts are attached as Exhibits G, H, I, and J.

73. Although the Act directs the Board to "determine by rule the methodology for establishing an upper payment limit," Colo. Rev. Stat. § 10-

16-1407(2), the Board never disclosed any methodology for determining the amount of the UPL for Enbrel. The Board's rule purporting to establish a "methodology" simply (i) restates the statutory factors the Board is required to consider and those it is prohibited from considering and (ii) lists ten different "price and cost metrics" that the Board "may consider," without specifying how the Board will use those metrics to establish an upper payment limit. 3 Colo. Code Regs. § 702-9.4.1(C).

74. The Board did not disclose a proposed UPL amount for Enbrel until August 22, 2025, at its third rulemaking hearing. At that hearing, the Board voted to amend the proposed UPL rule (which until that point had included a blank space where the specific price cap would eventually go) to set the UPL for Enbrel at $583.59 per unit.

75. The Board stated that this price was equivalent to the "maximum fair price" ("MFP") imposed by the Centers for Medicare and Medicaid Services under the federal Inflation Reduction Act, 42 U.S.C. § 1320f *et seq.*, for sales of Enbrel that are covered by Medicare.

76. The Board Chair acknowledged that this price was nearly 70% lower than Enbrel's current National Average Drug Acquisition Cost (or "NADAC"), a pricing benchmark that is intended to reflect prices paid by retail

pharmacies to acquire the drug.[19] The price is also significantly lower than Enbrel's current Wholesale Acquisition Cost.

77. The Board's uncritical adoption of the federal MFP reflected its failure to determine a methodology of its own for establishing an upper payment limit. As one Board member stated: "I know a lot of people are concerned. How are you going to come up with that price? What is the calculation? Where's the research? Well, in this instance, it was already done at that level" (referring to the federal MFP for Medicare sales).[20]

78. At the fourth and final rulemaking hearing, held on October 3, 2025, the Board amended the proposed rule to set the upper payment limit at $600.00 per unit. The Board members stated that the change from $583.59 to $600.00 was intended to "round up" from the federal MFP in order to provide "wiggle room" in case the MFP changed.[21]

79. At the same hearing, in response to a commenter who suggested that imposing a UPL would reduce incentives for drug companies to invest in developing and deploying innovative medicines, the Board Chair stated: "Enbrel was approved over 25 years ago, … so the company has had more than

[19] Ex. I at 18.

[20] *Id.* at 41.

[21] Ex. J at 23, 37–38, 48.

enough time to recoup the investment they made on that—the development of that drug."[22]

80. At the conclusion of the October 3 hearing, the Board (with Dr. Diab recused) voted to adopt its final rule setting the upper payment limit for Enbrel at $600.00 per unit.[23] The upper payment limit will take effect on January 1, 2027. *See* Ex. A.

81. As required by Colorado law, after the Board adopted the UPL rule, the rule was submitted to the Attorney General for his opinion as to its constitutionality and legality. *See* Colo. Rev. Stat. § 24-4-103(8)(b). The Attorney General approved the rule on October 23, 2025, and the rule was filed with the Secretary of State for publication in the Colorado Register that same day. It will be published in the Colorado Register on November 10, 2025.

Consequences of the Final Rule

82. If the Act and its application to Enbrel are not declared unlawful and enjoined, Amgen will suffer substantial and irreparable harm.

83. The Act states that an upper payment limit "applies to all purchases of and payer reimbursements for a prescription drug that is

[22] *Id.* at 82.

[23] *Id.* at 99–100.

dispensed or administered to individuals in the state in person, by mail, or by other means." *Id.* § 10-16-1407(5). On its face, this language indicates that the price cap applies to sales by Amgen itself, so long as the drug is eventually dispensed or administered in Colorado. If Amgen is forced to lower its prices for products destined for Colorado, that will obviously cause Amgen financial harm by decreasing its revenues.

84. Defendants have taken the position that the upper payment limit applies only to "downstream" transactions, including sales by Amgen's wholesalers and distributors to pharmacies, hospitals, and other healthcare providers.

85. In Amgen's prior lawsuit, this Court accepted Defendants' position and held that an upper payment limit "does not directly apply to a wholesaler's purchase from a manufacturer," but rather "applies directly only to downstream transactions," including "pharmacies and providers' purchases" from wholesalers. *Amgen Inc.*, 2025 WL 947474 at *6.

86. Even accepting Defendants' position does not change the fact that Amgen will suffer substantial, irreparable harm as a result of Colorado's imposition of an upper payment limit on Enbrel.

87. If wholesalers must sell Enbrel to pharmacies and providers at the UPL, which is significantly lower than WAC, those wholesalers will not

purchase Enbrel from Amgen at WAC unless Amgen reimburses them for the difference in price. Amgen's contracts with its wholesalers, standard industry practice, and basic economics all require Amgen to provide such reimbursement, which it normally does in the form of "chargebacks." Without such reimbursement, the wholesalers would lose money on each sale on Enbrel that is subject to the UPL. Buying high and selling low is not a viable business model in any industry, and certainly not for pharmaceutical wholesalers, which operate on extremely thin margins and generally do not have the capacity to absorb uncompensated discounts.

88. Accordingly, if the UPL set by the Board is allowed to take effect, there is no realistic chance that wholesalers will absorb the discount required to comply with the upper payment limit without passing the cost on to Amgen. Indeed, Amgen is contractually required to reimburse wholesalers for any such legally mandated discounts. Wholesalers will not purchase a drug at WAC (that is, the current list price), without any discount or reimbursement from Amgen, if those wholesalers must sell the drug at a price below WAC. Like any other rational economic actor, wholesalers will not agree to purchase a product for more than what they can lawfully recover from reselling that product.

89. The UPL will thus undoubtedly cause financial injury to Amgen because the UPL dictates the maximum net price that Amgen can charge

wholesalers.

90. Colorado is well aware that an upper payment limit will function as a limit on what a manufacturer can charge for that drug. Indeed, that is the Act's intended effect. As a leading sponsor of the Act explained, manufacturers will bear the cost of a UPL because wholesalers "will sell [the drug] to pharmacies or hospitals … at that lower price and then they will be made whole on the back-end by the pharmaceutical manufacturer." *Hearing on S.B. 21-175 Before H. Comm. on Health & Ins.*, 73d Sess. at 7:22:00–7:23:30 (Colo. 2021), *available at* https://tinyurl.com/3tas6ddc (statement of Rep. Kennedy).

91. The text of the Act reflects this commonsense reality. For example, it expressly recognizes that imposing a UPL on a drug may lead the drug's manufacturer to stop selling the drug in Colorado. Whenever the Board establishes an upper payment limit for a drug, it must "[i]nquire of manufacturers of the prescription drug as to whether each such manufacturer is able to make the prescription drug available for sale in the state" notwithstanding the UPL. Colo. Rev. Stat. § 10-16-1407(10); *see also id.* § 10-16-1408(4) (addressing situations where "a manufacturer refuses to make the drug available as a result of an upper payment limit established for the prescription drug by the [B]oard"); *id.* § 10-16-1412(1) (requiring advance written notice from "[a]ny manufacturer that intends to withdraw from sale or

distribution within the state a prescription drug for which the [B]oard has established an upper payment limit"). These provisions would make no sense if the manufacturer were not expected to bear the cost of the UPL.

92. The Board also has acknowledged this reality. For example, at the rulemaking hearing on May 23, 2025, the Board discussed the role of chargebacks in the supply chain and demonstrated its understanding that drug manufacturers must reimburse wholesalers for any discounts the wholesalers are required to provide as a result of a UPL. As one Board member noted, wholesalers "buy everything at one price [*i.e.*, the WAC] and then they submit documentation after the fact to get those chargebacks so that they get the accurate net price for their sales."[24] And, at a subsequent hearing, the Board chair asserted that the effective date of the rule would "give[] pharmacies and others time to talk to their manufacturers … to make it clear that they can't pay more than this Upper Payment Limit."[25]

93. Similarly, at the May 23, 2025 hearing, a wholesaler representative on the Board-appointed Advisory Council explained to Board members that if a wholesaler is required to sell a drug to "the downstream

[24] Ex. G at 56.

[25] Ex. J at 52.

customer, the pharmacy, the hospital, nursing home, et cetera" at a price below WAC, then "the manufacturer would make the wholesaler whole on a chargeback basis" to "make sure that [the wholesaler is] not buying at a higher cost [and] selling it at this lower cost."[26]

94. In addition to requiring Amgen to reduce the net price it charges wholesalers, the UPL will also cause severe market disruption, which will negatively impact Amgen's current contractual and business relationships. Some wholesalers may choose to purchase an alternative product not subject to an upper payment limit in place of Enbrel, which will cause Amgen to lose revenue. This market disruption will also force Amgen to incur administrative costs negotiating with wholesalers, distributors, and pharmacy benefit managers ("PBMs"). Amgen will also need to incur costs to modify its payment systems to account for the upper payment limit.

95. Amgen will begin incurring these costs well in advance of the January 1, 2027 effective date. For example, the process of negotiating Amgen's contracts with PBMs for 2027 will begin in late 2025 and continue into 2026. The Board has also stated that it is preparing a "communication plan" to notify insurance carriers, healthcare providers, and consumers about

[26] Ex. G at 59–60.

the UPL in advance of its effective date.[27]

96. In addition, as noted above, the statute requires the Board to inquire of Amgen whether it is able to make Enbrel available for sale in Colorado notwithstanding the UPL, and the Board's regulations state that "[m]anufacturers shall have 30 days to respond" to this inquiry. Colo. Rev. Stat. § 10-16-1407; 3 Colo. Code Regs. § 702-9:4.1(E)(1). At the hearing on October 3, 2025, Board staff stated that they are "currently drafting" the inquiry letter, suggesting that it may be sent at any time.[28]

97. Regardless of when the Board sends the inquiry letter, Amgen must provide written notice at least 180 days before withdrawing Enbrel from sale or distribution in Colorado or face a potential $500,000 penalty. Colo. Rev. Stat. § 10-16-1412(1). In order to avoid being subject to the UPL when it takes effect on January 1, 2027, Amgen would have to submit such a notice no later than July 5, 2026.

98. Amgen will be unable to recover financial losses it suffers as a result of the Act. Because Colorado is entitled to sovereign immunity under the Eleventh Amendment, even if Amgen ultimately prevails in this lawsuit,

[27] Ex. J at 101.

[28] *Id.* at 102.

Amgen will not be able to obtain damages from the state. Amgen's monetary harm is therefore irreparable. *See Chamber of Com. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury.").

99. Moreover, in addition to forcing Amgen to lower the net prices it charges wholesalers, the UPL will cause broader market disruption that will negatively impact Amgen's consumer goodwill and business relationships. Such "lost goodwill, lost customer trust and damage to reputation" independently constitute irreparable harm. *Salomon & Ludwin, LLC v. Winters*, 150 F.4th 268, 378 n.7 (4th Cir. 2025).

CLAIMS FOR RELIEF

Count 1
Preemption Under the Federal Patent Laws

100. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

101. Under the Supremacy Clause of the United States Constitution, federal statutes are "the supreme Law of the Land." U.S. Const. art. VI, cl. 2.

102. It is well established that state law is preempted "where it regulates conduct in a field that Congress intended the Federal Government

to occupy exclusively" or where it "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) (quoting *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941)). This inquiry "ranges beyond the literal text" of the federal statute and requires an examination of its "'purpose and intended effects.'" *Biotech. Indus. Org. v. District of Columbia* (*BIO*), 496 F.3d 1362, 1372 (Fed. Cir. 2007) (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)).

103. Under the U.S. Constitution, the power to regulate patent rights is expressly granted to Congress, not reserved for the States. U.S. Const. art I, § 8, cl. 8. "The federal patent system … embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats*, 489 U.S. at 150–51. The "pecuniary rewards stemming from the patent right" incentivize the costly research and development that drives technological innovation. *BIO*, 496 F.3d at 1372.

104. As reflected in the enactment of the Hatch-Waxman Act and the BPCIA, Congress has taken special care to safeguard those incentives for innovation in the pharmaceutical field and has struck a careful and deliberate balance, ensuring that those who develop innovative medicines are rewarded

with a period of federal patent exclusivity and pricing discretion, while encouraging generic and biosimilar competition after the end of the relevant patent terms.

105. Because it contains no exemption for patented drugs like Enbrel, Colorado's price-control scheme frustrates the purposes and objectives of the federal patent laws by "re-balanc[ing] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374. A state price-setting process for patented drugs is preempted by federal law because it is fundamentally inconsistent with the congressional design.

106. As the Federal Circuit recognized in striking down another state law that sought to cap the prices of patented drugs, "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." *Id.* at 1373. A state cannot take it upon itself to alter that balance by preventing a patent owner or licensee from charging prices that reflect its federally guaranteed patent exclusivity. "The underlying determination about the proper balance between innovators' profit and consumer access to medication … is exclusively one for Congress." *Id.* at 1374.

107. The Board's conduct in imposing a UPL on Enbrel and the Board's related proceedings further confirm that the Board is attempting to alter the

balance Congress struck when calibrating the federal patent laws. For example, the Board's affordability report emphasized Enbrel's patent protection and observed that "such intellectual property rights can be associated with increased drug prices."[29] In addition, a Board member expressly acknowledged that the Board selected Enbrel, rather than a competitor, for an affordability review because unlike Enbrel, the competitor is subject to biosimilar competition and no longer patent-protected. The Board has thus targeted Enbrel specifically because it is still on patent.

108. Shortly before the Board adopted the Enbrel UPL rule, the Board Chair declared that it was appropriate to reduce Amgen's profits from Enbrel because "the company has had more than enough time to recoup [its] investment."[30] In other words, the Chair disagreed with Congress's decision to provide Amgen the economic rewards associated with patent exclusivity through 2029 and admitted that the Board is seeking to "re-balance the statutory framework of rewards and incentives" that applies to Enbrel under federal law. *BIO*, 496 F.3d at 1374.

109. Accordingly, the Act and its application to Enbrel implicate both

[29] Ex. C at C-9; Ex. D at C-11.

[30] Ex. J at 82.

field and conflict preemption and are preempted by the federal patent laws.

Count 2
Violation of Due Process

110. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

111. The Due Process Clause of the Fourteenth Amendment prohibits the government from depriving a person of "life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. Plaintiffs have a protected property interest in their patent-protected medication, Enbrel, which includes the right to determine the price at which they will sell Enbrel. *See Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (explaining 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).

112. At its core, the Due Process Clause requires notice and an opportunity to be heard "at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)); *see C1.G ex rel. C.G. v. Siegfried*, 38 F.4th 1270, 1280 (10th Cir. 2022). A meaningful opportunity to be heard requires meaningful standards to limit and channel the exercise of governmental power.

Meaningful standards are also necessary to avoid arbitrary decisionmaking and ensure that governmental officials are acting in the broader public interest and not for capricious or impermissible reasons.

113. The Act, as implemented by the Board, violates the Due Process Clause because it provides no standards for the Board to apply either when determining whether a drug is "unaffordable for Colorado consumers" or when setting an upper payment limit. Although the statute provides an assortment of factors for the Board to consider in making those determinations, the statute does not explain how the Board should assess and weigh those factors. And the Board's regulations largely echo the statute without providing meaningful standards to guide and limit the Board's discretion.

114. As a result, the Act fails to provide drug manufacturers with a meaningful opportunity to be heard, encourages arbitrary and discriminatory enforcement, and creates an unacceptable risk of erroneous deprivations of manufacturers' property interests.

115. The Act also violates the more specific due-process principles that courts have applied in the context of administrative price-control schemes.

116. Due process requires that the procedures employed by agencies be designed to ensure that prices set by the government are, at minimum, "just and reasonable" and not unduly discriminatory or "'confiscatory.'" *Mich. Bell*

Tel. Co. v. Engler, 257 F.3d 587, 592–93 (6th Cir. 2001) (quoting *Duquesne Light Co. v. Barasch*, 488 U.S. 299, 307 (1989)); *Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990), *as amended* (Nov. 8, 1990). Due process also requires a mechanism through which a regulated entity can "challenge the imposition of rates which may be confiscatory" as well as adequate safeguards to "ensur[e] a constitutional rate of return." *Mich. Bell*, 257 F.3d at 592–93.

117. Here, as discussed above, the Act does not provide any standards to ensure a constitutional rate of return for drug manufacturers. Indeed, the law does not even include the manufacturer's return on investment as one of the many factors the Board is required to consider when determining affordability and setting an upper payment limit, and the Board accordingly did not consider it when setting a UPL for Enbrel. The Act therefore fails to provide Plaintiffs with due process.

Count 3
Violation of the Commerce Clause

118. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

119. The Commerce Clause of the Constitution grants Congress the power to regulate interstate commerce. U.S. Const. art. I, § 8, cl. 3. As the Supreme Court has long recognized, this 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) (brackets omitted) (quoting *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995)).

120. Under this "dormant Commerce Clause" doctrine, 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."); *Daniels Sharpsmart, Inc. v. Smith*, 889 F.3d 608, 615 (9th Cir. 2018) ("The mere fact that some nexus to a state exists will not justify regulation of wholly out-of-state transactions.").

121. The Act violates that extraterritoriality principle because it purports to regulate transactions that occur entirely outside of the State of Colorado. Under the Act, 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 in person, by mail, or by other means." Colo. Rev. Stat. § 10-16-1407(5). By its terms, this language

applies the upper payment limit even to wholly out-of-state, upstream transactions, so long as the drug is eventually dispensed or administered in Colorado. Colorado may not directly regulate a sale that occurs in another state simply because the product may eventually make its way into Colorado.

122. In briefing in the U.S. Court of Appeals for the Federal Circuit, Defendants have asserted that an upper payment limit applies only to "transactions that *take place in Colorado* for a drug also dispensed or distributed in the state." Response Br. 14, *Amgen Inc. v. Colo. Prescription Drug Affordability Rev. Bd.*, No. 25-1641 (Fed. Cir. Aug. 28, 2025), Dkt. 23 (emphasis added). But nothing in the statute or regulations prevents the UPL from applying to sales that take place outside of Colorado where the drug later makes its way into Colorado. On the contrary, the Board's regulation states that a UPL "applies to any pharmacy … or provider's purchase of a prescription drug *that is dispensed or administered to a Colorado consumer* in person, by mail, or by other means." 3 Colo. Code Regs. § 702-9:4.2(C)(1)–(2) (emphasis added). And Defendants previously told this Court that a UPL would apply to "pharmacies' and providers' purchase of a drug" outside of Colorado "if they decide to dispense or administer the drug in Colorado." Summ. J. Reply at 20, *Amgen*, No. 1:24-cv-810 (D. Colo. Oct. 4, 2024), Dkt. 42 (emphasis omitted).

123. As the Fourth Circuit recognized in striking down a similar drug-

pricing law, a state law is invalid under the Commerce Clause if it attempts to "control[ ] the price of transactions that occur wholly outside the state." *Ass'n for Accessible Meds.*, 887 F.3d at 671; *see id.* at 672 ("[T]he Act is effectively a price control statute that instructs manufacturers and wholesale distributors as to the prices they are permitted to charge in transactions that do not take place in Maryland."). The Eighth Circuit recently agreed, striking down a similar Minnesota law and rejecting the argument "that because the drugs must eventually end up in Minnesota" for the price cap to apply, the law "does not set the price of transactions in other states." *Ass'n for Accessible Meds. v. Ellison*, 140 F.4th 957, 960 (8th Cir. 2025).

124. Accordingly, insofar as Colorado's price-control law directly regulates the prices charged in wholly out-of-state transactions, it is per se invalid under the Commerce Clause.

125. Moreover, even if Colorado's attempt to directly regulate out-of-state transactions were not per se invalid, it would still violate the Commerce Clause because the burden imposed on interstate commerce by such extraterritorial regulation "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. v. Ellison*, 704 F. Supp. 3d 947, 960 (D. Minn. 2023).

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

1. A declaration that the Act is unconstitutional and void as applied to patented drugs because it conflicts with the federal patent laws, and injunctive relief preventing Defendants from enforcing the Act as to Enbrel while Enbrel remains patent-protected.

2. A declaration that the Act is unconstitutional and void because it denies Plaintiffs and other interested parties due process of law, and injunctive relief preventing Defendants from enforcing the Act as to Enbrel.

3. A declaration that the Act is unconstitutional and void insofar as it regulates wholly out-of-state transactions, and injunctive relief preventing Defendants from enforcing the Act with respect to such transactions.

4. An award of costs and attorneys' fees.

5. Such other and further relief as may be just and proper.

Dated: October 30, 2025

Respectfully submitted,

/s/ Paul Alessio Mezzina
Ashley C. Parrish
(D.C. Bar No. 464683)
Paul Alessio Mezzina
(D.C. Bar No. 999325)
Kelly Nicole Reeves
(D.C. Bar No. 471923)
Alexander Kazam
(D.C. Bar No. 1708188)
Nicholas A. Mecsas-Faxon
(D.C. Bar No. 1779269)
King & Spalding LLP
1700 Pennsylvania Avenue NW
Suite 900
Washington, DC 20006
Tel: (202) 737-0500
aparrish@kslaw.com
pmezzina@kslaw.com
nreeves@kslaw.com
akazam@kslaw.com
nmecsas-faxon@kslaw.com

Cliff Stricklin
(Colo. Bar No. 39725)
King & Spalding LLP
1401 Lawrence Street, Suite 1900
Denver, CO 80202
Tel: (720) 535-2300
cstricklin@kslaw.com

Counsel for Plaintiffs

LIST OF EXHIBITS

Exhibit A	Enbrel UPL Rule (Oct. 3, 2025)
Exhibit B	CO PDAB 2023 Eligible Drug Dashboard: Eligible List Summary (Oct. 19, 2023)
Exhibit C	DRAFT Enbrel Affordability Review Summary Report (Feb. 9, 2024)
Exhibit D	Enbrel Affordability Review Summary Report (Feb. 23, 2024)
Exhibit E	Transcript of Feb. 16, 2024, Colorado PDAB Hearing
Exhibit F	Transcript of Feb. 23, 2024, Colorado PDAB Hearing
Exhibit G	Transcript of May 23, 2025, Colorado PDAB Hearing
Exhibit H	Transcript of July 11, 2025, Colorado PDAB Hearing
Exhibit I	Transcript of Aug. 22, 2025, Colorado PDAB Hearing
Exhibit J	Transcript of Oct. 3, 2025, Colorado PDAB Hearing