UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO

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

Plaintiffs,

v.

COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD;
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. 1:24-cv-00810

COMPLAINT

PRELIMINARY STATEMENT

1. Innovative drugs have enriched the lives of countless Coloradans. One of those drugs, Enbrel®, provides disease-transforming and life-changing relief to more than 3,000 Coloradans every year 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 for years or even decades with lower pain, less 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 an "upper payment limit." The Board's decision, and the statutory scheme on which it is based, are unconstitutional because they conflict with federal law, violate basic requirements of due process, and impermissibly seek to regulate outside of Colorado. In violating both the federal Constitution and federal laws, the Board's decision puts in jeopardy access to Enbrel® and other innovative drugs, endangering the lives and well-being of thousands of

Coloradans with serious medical conditions.

3. Plaintiffs Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited bring this action for declaratory and injunctive relief against the Colorado Prescription Drug Affordability Review Board, 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

4. This lawsuit seeks to have the Court declare invalid, and enjoin the enforcement of, a facially unconstitutional Colorado law that 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.*

5. Enacted as Senate Bill 21-175, and amended by House Bill 23-1225, the stated purpose of the 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.

6. 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.*

7. 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. *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" and what the "upper payment limit" for a drug should be.

8. That "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 in person, by mail, or by other means." *Id.* The upper payment limit thus applies even to "upstream" transactions—transactions that occur entirely outside of Colorado, but where the drug involved in the transaction is later dispensed or administered in Colorado.

9. The Act does not contain any exemption for prescription drugs that are patented under federal law. In fact, in conducting affordability reviews, the Board stated that it is targeting drugs that are protected by the federal patent laws, like Enbrel®, because patents limit competition. This limiting of competition is, of course, a deliberate element of federal law. Patents reward inventors with the ability to charge prices that can be used to help fund further important investment—for example, in reliable manufacturing of the drug itself—and facilitate additional innovation during and beyond the term of the patent.

10. The Board's novel regulatory scheme violates the U.S. Constitution in at least four 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 (also 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 very 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 Supremacy Clause for the additional reason that Colorado's statute applies the "upper payment limit" so broadly as to encompass even federal payors such as Medicare. Federal law preempts state laws that impermissibly interfere with the federal government's ability to control its own payment and coverage decisions under federal healthcare

programs.[1]

14. *Fourth*, the Act violates the Commerce Clause because it regulates commercial transactions that occur entirely outside of the state of Colorado.

15. For these reasons, and as further explained below, this Court should declare the Act unconstitutional and enjoin its enforcement against Plaintiffs.

PARTIES

16. Plaintiff Amgen Inc. ("Amgen") is a biopharmaceutical company that discovers, develops, manufactures, and delivers innovative medicines to fight some of the world's toughest diseases. Amgen 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 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.

[1] A policy document the Board issued in January 2023 states without elaboration that "[a]n upper payment limit does not apply to [a] purchase or reimbursement made by Medicare." Ex. A at 2 (Prescription Drug Affordability Rev. Bd., PDAB Pol'y No. 05, Upper Payment Limit Policy & Procedure (Jan. 13, 2023), *available at* https://drive.google.com/drive/folders/1SVcgHEv4CNgyspCnm79VnqFkJjG2PaDH). This document is not legally binding, does not purport to supersede or limit the statute, and thus does not provide legally adequate assurance against preempted applications of Colorado's price-control law.

17. Plaintiff Immunex Corporation ("Immunex") is a wholly owned subsidiary of Amgen 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.

18. Plaintiff Amgen Manufacturing, Limited ("AML") is an indirect wholly owned subsidiary of Amgen. 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, all the while ensuring top-quality operations and innovative enhancements to the manufacturing process. AML is a corporation organized and existing under the laws of the territory of Bermuda, with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777.

19. Defendant Prescription Drug Affordability Review Board is a five-member body within the Colorado Division of Insurance charged with

determining whether certain prescription drugs are "unaffordable for Colorado consumers" and establishing "upper payment limits" for drugs it declares unaffordable. Colo. Rev. Stat. §§ 10-16-1402, 10-16-1403(1), 10-16-1406(3), 10-16-1407(1)(a). The Board is also required to "promulgate rules as necessary … for the implementation" of the Act. *Id.* § 10-16-1403(5). The Board has its principal office in Denver, Colorado.

20. 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.

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

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

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

24. 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.

25. 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.

26. 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." Colo. Rev. Stat. § 10-16-1411(3). Attorney General Weiser maintains an office in Denver, Colorado.

JURISDICTION AND VENUE

27. 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.

28. This Court has personal jurisdiction over Defendants because they are domiciled in Colorado, and because the enactment and enforcement of the state laws at issue in this lawsuit occurred and continues to occur within Colorado.

29. 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.

30. 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

31. 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).

32. 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.

33. 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. As explained below, that is especially true in the context of pharmaceutical patents.

34. The patent laws protect not only innovative products, but also innovative methods that may enhance the usefulness or effectiveness of existing products or processes. *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor ….").

35. 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,[2] the process takes an average of 10 to 15 years,[3] and only about 1 in 5,000 potential new drugs actually obtain approval and reach patients.[4]

36. In 1984, recognizing the unique challenges posed by the costly drug-development process, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly 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 time-consuming, but essential, testing required by the Food and Drug

[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.

Administration." Remarks on Signing S. 1538 into Law, September 24, 1984, 20 Weekly Comp. Pres. Doc. 1359–60 (Oct. 1, 1984).

37. 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 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).

38. In this way, 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

39. 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).

40. 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).

41. 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. Colo. Rev. Stat. § 10-16-1406(1).

42. 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 "health 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).

43. 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). The Board has promulgated rules specifying that it will consider additional factors, including "Rebates, Discounts, and Price Concessions"; "Health Equity Factors"; relevant 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).

44. 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).

45. 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.

46. 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).

47. 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).

48. The Board's rules regarding the methodology for establishing upper payment limits state that the Board "shall review" the factors specified in § 10-16-1407(2). 3 Colo. Code Regs. § 702-9:4.1(C)(2). The rules elaborate on how the Board might, in its discretion, consider those statutory factors. For example, "[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).

49. 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

Plaintiffs' Patent-Protected Drug Enbrel®

50. Enbrel®, first approved by the Food and Drug Administration in 1998, 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.

51. 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.

52. 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.

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

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

55. 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).

The Board's Proceedings Regarding Enbrel®

56. 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.[5]

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

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

59. 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.[6] The report contrasted this with "[t]wo of Enbrel's therapeutic alternatives, Humira and

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[5] 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.

[6] Ex. B at 26 (Colo. Prescription Drug Affordability Bd., DRAFT 2023 Affordability Review Summary Report: Enbrel (Feb. 9, 2024), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

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."[7]

60. Further emphasizing Enbrel®'s patent protection, the report included an appendix section specifically devoted to the topic of "Patents and Exclusivity."[8] 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 prices, delayed availability, and increased costs to consumers and governments."[9] 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."[10] 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

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

[8] *Id.*

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

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

'522 patents against challenges from potential competitors seeking to market biosimilar drugs prior to the expiration of those patents in 2029.[11]

61. 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." At the meeting, one of the members remarked that even though an Enbrel® competitor had historically been more expensive than Enbrel®—in fact, it 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 competition (*i.e.*, its patent exclusivity period had ended).

62. 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 approve the final affordability review summary report for Enbrel.® The Board then voted—without further deliberation and without responding to public comments—to select Enbrel® for establishment of an upper payment limit and directed its staff to initiate a rulemaking to determine the precise

[11] *Id.*

[12] *See* Ex. C (Colo. Div. of Ins., *CO PDAB 2023 Eligible Drug Dashboard: Eligible List Summary* (Oct. 19, 2023), https://public.tableau.com/app/profile/colorado.division.of.insurance/viz/COPDAB2023EligibleDrugDashboard/1_EligibleListSummary).

amount of that upper payment limit. The rulemaking is to take a maximum of 180 days, *see* Colo. Rev. Stat. § 24-4-103(4)(d), and the upper payment limit is expected to become effective six months after the Board promulgates a rule establishing the limit, *see id.* § 10-16-1407(5).

63. 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."[13] The final report was otherwise identical to the draft report in all relevant respects, including the discussion of Enbrel®'s patents.[14]

64. While the specific amount of the upper payment limit for Enbrel® is still being determined, the Board's decisions to date mean that Enbrel® will be subject to an upper payment limit that will prevent Plaintiffs from realizing the full benefit of their federal patent exclusivity.

65. Moreover, the Board's determination that Enbrel® is

[13] *See* Ex. D at 2–3 (Colo. Prescription Drug Affordability Bd., 2023 Affordability Review Summary Report: Enbrel (Feb. 23, 2024), *available at* https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board).

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

"unaffordable" and its decision to select Enbrel® for establishment of an upper payment limit are already harming Plaintiffs by, for example, causing them to incur substantial costs to participate and defend their interests in a preempted state price-setting process that violates the U.S. Constitution and federal law and casting a shadow of uncertainty over Plaintiffs' longstanding contractual relationships involving Enbrel®.

CLAIMS FOR RELIEF

Count 1
Preemption Under the Federal Patent Laws

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

67. 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.

68. Under well-established federal "conflict preemption" principles, no state law may "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *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)).

69. "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.

70. 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.

71. 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,

regardless of its outcome, because it is fundamentally inconsistent with the congressional design and imposes hardships of expense, delay, and uncertainty on the very parties the patent laws are designed to protect.

72. 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.

73. The Board's conduct in selecting Enbrel® for an affordability review and performing that review further confirms 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."[15] In addition, a Board

[15] Ex. B at C-9; Ex. D at C-11.

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.

74. Accordingly, the Act stands as an obstacle to Congress's clear purposes and objectives and is preempted by the federal patent laws.

Count 2
Violation of Due Process

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

76. 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®.

77. 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).

78. 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.

79. 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.

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

81. 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); *see 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.

82. 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. The Act therefore fails to provide Plaintiffs with due process.

Count 3
Interference with Federal Healthcare Programs

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

84. The Act is also preempted insofar as it purports to dictate the prices that federal healthcare programs—such as Medicare, TRICARE, the Veterans Health Administration, and the Federal Employees Health Benefits Program—are required to pay for Enbrel and other prescription drugs on behalf of beneficiaries of those programs. In doing so, the Act directly regulates federal activities and interferes with the operation of federal healthcare programs. It is well-settled that "the activities of the Federal Government are free from regulation by any state." *Mayo v. United States*, 319 U.S. 441, 445 (1943); *see United States v. Sup. Ct.*, 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" (quotation marks omitted)).

85. Moreover, the Act is expressly preempted under the "sweeping" preemption provisions applicable to the federal Medicare Part C and D programs. *Pharm. Care Mgmt. Ass'n v. Mulready* ("*PCMA*"), 78 F.4th 1183, 1206 (10th Cir. 2023).

86. Medicare Parts C and D are public-private partnerships between the federal Centers for Medicare & Medicaid Services and private insurers (called plan sponsors). Plan sponsors may offer prescription-drug coverage to Medicare recipients and must abide by federal statutes and regulations in doing so. Against that "backdrop of extensive federal regulation," Medicare Parts C and D have "broad preemption clause[s]." *Id.* at 1205. Those clauses provide, in relevant part, that "[t]he 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] which are offered by [plan sponsors] under [Part C or D]." 42 U.S.C. § 1395w-26(b)(3) (Part C); *see id.* § 1395w-112(g) (incorporating same preemption clause into Part D). The Tenth Circuit has held that this "sweeping" preemption 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.

87. These principles make clear that Colorado's price-control law is preempted insofar as it purports to dictate the prices that Medicare and other federal healthcare programs must pay for prescription drugs on behalf of beneficiaries of those programs. Under Colorado's law, an 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." Colo. Rev. Stat. § 10-16-1407(5) (emphasis added). The law does not exempt federal payors; nor does it make their participation optional.

88. Accordingly, the Act impermissibly regulates "with respect to" Medicare plans. *PCMA*, 78 F.4th at 1208 (quotation marks omitted). And it impermissibly subjects all federal healthcare 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).

Count 4
Violation of the Commerce Clause

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

90. 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)).

91. 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., Inc.*, 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.").

92. 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.

93. 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."); *see also Ass'n for Accessible Meds. v. Ellison*, 2023 WL 8374586, at *3 (D. Minn. Dec. 4, 2023) (holding that Minnesota could not "directly regulate[ ] extraterritorial sales of drugs … simply because the product eventually makes its way into Minnesota"), *appeal docketed*, No. 24-1019 (8th Cir. Jan. 20, 2024).

94. 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. 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.*, 2023 WL 8374586, at *9.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

1. A declaration that the Act is unconstitutional and void because it conflicts with the federal patent laws, and an injunction preventing Defendants from enforcing the Act as to patented drugs.

2. A declaration that the Act is unconstitutional and void because it denies Plaintiffs due process of law, and an injunction preventing Defendants from enforcing the Act against Plaintiffs.

3. A declaration that the Act is unconstitutional and void insofar as it regulates transactions involving federal healthcare programs, and an injunction preventing Defendants from enforcing the Act with respect to such transactions.

4. A declaration that the Act is unconstitutional and void insofar as it regulates wholly out-of-state transactions, and an injunction

preventing Defendants from enforcing the Act with respect to such transactions.

5. An award of costs and attorneys' fees.

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

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Respectfully submitted,

/s/ Ashley C. Parrish

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