IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:25-cv-3452-DDD-STV

AMGEN INC, et al.,

Plaintiffs,

v.

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

Defendants.

ANSWER

Defendants Gail Mizner, M.D., Sami Diab, M.D., Amarylis Gutierrez, Pharm.D., Catherine Harshbarger, and James Justin Vandenberg, Pharm.D., in their official capacities as Board members of the Colorado Prescription Drug Affordability Review Board; Michael Conway, in his official capacity as Commissioner of Insurance (the "Commissioner"); and Philip J. Weiser, in his official capacity as Attorney General of the State of Colorado (the "Attorney General") (collectively, "Defendants"), hereby submit their Answer to Plaintiffs' Amgen Inc., Immunex Corporation, and Amgen Manufacturing, Limited LLC's ("Plaintiffs") Complaint (ECF 1).

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief after the truth of the allegations of paragraph 1, and therefore, deny them.

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.

Defendants' Response: Defendants admit, pursuant to 3 Colo. Code Regs. § 702-9:4.3, the Enbrel UPL rule will take effect on January 1, 2027. Defendants deny the remaining allegations in paragraph 2.

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.

Defendants' Response: Defendants deny the allegations in paragraph 3.

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:

Defendants' Response: Defendants admit that Plaintiffs seek declaratory and injunctive relief by their Complaint and the Board members (in their official capacities), the Commissioner (in his official capacity), and the Attorney General (in his official capacity) in their Complaint.

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.

Defendants' Response: Defendants deny the allegations in paragraph 5.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 6.

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.*

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 7.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 8.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401

to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 9.

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.

Defendants' Response: Defendants deny the allegations in paragraph 10.

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.

Defendants' Response: Defendants deny the allegations in paragraph 11.

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.

Defendants' Response: Defendants deny the allegations in paragraph 12.

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.

Defendants' Response: Defendants deny the allegations in paragraph 13.

14. For these reasons, and as further explained below, this Court should declare the Act unconstitutional and enjoin its enforcement as to Enbrel.

Defendants' Response: Defendants deny the allegations in paragraph 14.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 15 and, therefore, deny them.

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.

Defendants' Response: Defendants admit that Amgen or its subsidiaries manufacture Enbrel. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 16 and, therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of allegations of paragraph 17 and, therefore, deny them.

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.

Defendants' Response: Defendants admit the allegations in paragraph 18. However, Dr. Gail Mizner resigned from the Prescription Drug Affordability Review Board on November 15, 2025. Defendants will file a notice of substitution of party pursuant to Fed. R. Civ. P. 25(d) upon appointment of the successor Board member.

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.

Defendants' Response: Defendants admit the allegations in paragraph 19.

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

Defendants' Response: Defendants admit that Defendant Amarylis Gutierrez, PharmD, is sued in her official capacity as a member of the Prescription Drug Affordability Review Board. Defendants deny the remaining allegations in paragraph 20.

21. Defendant Catherine Harshbarger, of Holyoke, Colorado, is sued in her

official capacity as a member of the Prescription Drug Affordability Review Board.

Defendants' Response: Defendants admit that Defendant Catherine Harshbarger is sued in her official capacity as a member of the Prescription Drug Affordability Review Board. Defendants deny the remaining allegations in paragraph 21.

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.

Defendants' Response: Defendants admit the allegations in paragraph 22.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Commissioner of Insurance maintains an office in Denver, Colorado. Defendants deny that the

Commissioner of Insurance exercises decision-making authority over the Board, which is authorized with independent decision-making as a type 1 entity under state law. C.R.S. § 10-16-1402(1). Defendants deny the remaining allegations in paragraph 23.

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.

Defendants' Response: Defendants admit the allegations of paragraph 24.

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.

Defendants' Response: Defendants deny the allegations in paragraph 25.

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.

Defendants' Response: Defendants admit that Plaintiffs purport to invoke the jurisdiction of this Court. Defendants deny the remaining allegations in paragraph 26.

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.

Defendants' Response: Defendants deny the allegations in paragraph 27.

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.

Defendants' Response: Defendants admit that Plaintiffs purport to invoke the venue of this Court. Defendants admit that at least one Defendant is a resident of the State in which this District is located. Defendants deny the remaining allegations in paragraph 28.

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).

Defendants' Response: Defendants admit that the U.S. Constitution gives Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Defendants also admit Plaintiffs cite *Mazer v. Stein*, 347 U.S. 201 (1954), and *Eldred v. Ashcroft*, 537 U.S. 186 (2003), and refer to those cases for their contents. Defendants deny the remaining allegations in paragraph 29.

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.

Defendants' Response: Defendants admit that patent law is codified in Title 35 of the United States Code, 35 U.S.C. § 1 *et seq*., and refer to those statutes for their contents. Defendants also admit Plaintiffs cite *King Instruments Corp. v. Perego*, 65 F.3d 941 (Fed. Cir. 1995), and refer to that case for its contents. Defendants deny the remaining allegations in paragraph 30.

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.

Defendants' Response: Defendants admit Plaintiffs cite *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), and refer to that case for its contents. Defendants deny the remaining allegations in paragraph 31.

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 obtains approval and reaches patients.[3]

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 32 and the articles referenced in footnotes 1-3 and, therefore, deny them.

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).

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

Defendants' Response: Defendants admit that Congress passed the Hatch-Waxman Act and refer to that act for its contents. Defendants deny the remaining allegations in paragraph 33.

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 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).

Defendants' Response: Defendants admit that Congress passed the Hatch-Waxman Act and refer to that act for its contents. Defendants admit that Congress passed the Biologics Price Competition and Innovation Act of 2009 and refer to that act for its contents. Defendants deny the remaining allegations in paragraph 34.

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.

Defendants' Response: Defendants deny the allegations of paragraph 35.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 36.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 37.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 38.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq.*, and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 39.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq.*, and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 40.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq.*, and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 41.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated

rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq.*, and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 42.

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.

Defendants' Response: Defendants deny the allegations in paragraph 43.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 44.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 45.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401

to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 46.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 47.

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.

Defendants' Response: Defendants admit that Enbrel is approved by the Food and Drug Administration to treat certain diseases including rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Defendants also admit that the Board's final affordability review report for Enbrel found that Enbrel can help people with moderate to severe rheumatoid arthritis or psoriatic arthritis reduce joint pain, prevent irreversible joint damage, and improve their physical function and overall quality of life. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 48 and, therefore, deny them.

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.

Defendants' Response: Defendants admit that Enbrel is a biologic drug, and that its active ingredient is a fusion protein called etanercept. Defendants admit Etanercept works by attaching to a protein in the body called "tumor necrosis factor" (TNF) and thereby inhibiting TNF's inflammatory activity. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 49 and, therefore, deny them.

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.

Defendants' Response: Defendants admit that Enbrel is covered by the '182 and '522 patents. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 50 and, therefore, deny them.

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

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 51, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 52, and therefore, deny them.

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.).

Defendants' Response: Defendants admit that the Federal Circuit issued a decision in *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020), and refer to that decision for its contents. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 53, and therefore, deny them.

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.

Defendants' Response: Defendants admit the allegations in paragraph 54.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 55, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 56, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 57, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 58, and therefore, deny them.

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]

Defendants' Response: Defendants admit the allegations of paragraph 59.

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).

Defendants' Response: Defendants deny the allegations of paragraph 60.

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.

Defendants' Response: Defendants admit that on August 4, 2023, the Board selected five brand-name drugs for affordability reviews, including Enbrel. Defendants deny the remaining allegations of paragraph 61.

62. 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

[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.

limit.

Defendants' Response: Defendants admit that the Board published its draft affordability review report in February 2024, which included a summary report, in addition to fifteen appendices, containing detailed information, and refer to those documents for their contents. Defendants deny the remaining allegations in paragraph 62.

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]

Defendants' Response: Defendants admit that the Board published its draft affordability review report in February 2024, which included a summary report, in addition to fifteen appendices, containing detailed information, and refer to those documents for their contents. Defendants deny the remaining allegations in paragraph 63.

64. Further emphasizing Enbrel's patent protection, the report included an appendix section specifically devoted to the topic of "Patents and Exclusivity."[7] The

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[5] Ex. C at 26.
[6] *Id.*
[7] *Id.* at C-9 to C-11.

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."[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]

Defendants' Response: Defendants admit that the Board published its draft affordability review report in February 2024, which included a summary report, in addition to fifteen appendices, containing detailed information, and refer to those documents for their contents. Defendants deny the remaining allegations in paragraph 64.

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

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

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

Defendants' Response: Defendants admit that on February 16, 2024, the Board held a meeting at which four of its members voted to determine that use of Enbrel, consistent with the labeling approved by the FDA or with standard medical practice, was unaffordable for Colorado consumers. Defendants also admit that, in its February 16, 2024, deliberations regarding Enbrel's unaffordability, the Board discussed Enbrel's therapeutic alternatives. Defendants deny the remaining allegations in paragraph 65.

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]

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[11] *Id.* at C-11.
[12] *Id.*
[13] Ex. E at 33–34.
[14] Ex. F at 21–22.
[15] *Id.* at 36–37.

Defendants' Response: Defendants admit that on February 23, 2024, the Board held a meeting at which three of its members voted to approve the final affordability review report for Enbrel, which includes a summary report, as well as fifteen appendices, containing detailed information. Defendants admit that the Board voted to select Enbrel for the potential establishment of an upper payment limit and directed its staff to initiate rulemaking with the Secretary of State for the Board to hold its first rulemaking hearing in a future meeting that accommodates the Board's overall schedule. Defendants deny the remaining allegations in paragraph 66.

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]

Defendants' Response: Defendants admit that the Board published the Board's final affordability review report for Enbrel on March 21, 2024, and that this report contained a section titled "Board Deliberation and Vote Summary." Defendants admit that in the Board Deliberation and Vote Summary, "utilization of therapeutic alternatives and availability of biosimilars" was one of many factors

[16] *See* Ex. D at 2–3.
[17] *See id.* at 25 and C-11 to C-13.

relied on by the Board in reaching its determination. Defendants deny the remaining allegations in paragraph 67.

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]

Defendants' Response: Defendants admit that Amgen sued Defendants in March 2024 in *Amgen Inc. et al. v. Mizner et al.*, No. 1:24-cv-810 (D. Colo.), and refer to that case for its contents. Defendants deny the remaining allegations in paragraph 68.

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

[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.

of subject matter jurisdiction. *Amgen Inc. v. Mizner*, 2025 WL 947474 (D. Colo.), appeal docketed, No. 25-1641 (Fed. Cir. Apr. 14, 2025).

Defendants' Response: Defendants admit that on March 28, 2025, the District of Colorado issued a decision in *Amgen Inc. et al. v. Mizner et al.*, No. 1:24-cv-810, 2025 WL 947474 (D. Colo. Mar. 28, 2025), and refer to that decision for its contents.

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 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.*

Defendants' Response: Defendants admit that on March 28, 2025, the District of Colorado issued a decision in *Amgen Inc. et al. v. Mizner et al.*, No. 1:24-cv-810, 2025 WL 947474 (D. Colo. Mar. 28, 2025), and refer to that decision for its contents.

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.*

Defendants' Response: Defendants admit that on March 28, 2025, the District of Colorado issued a decision in *Amgen Inc. et al. v. Mizner et al.*, No. 1:24-cv-810, 2025 WL 947474 (D. Colo. Mar. 28, 2025), and refer to that decision for its contents.

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.

Defendants' Response: Defendants admit the availability of the video recordings for the Board's four rulemaking hearings for Enbrel on May 23, July 11, August 22, and October 3, 2025, respectively. Defendants deny the remaining allegations in paragraph 72.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 73.

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.

Defendants' Response: Defendants admit that that Board voted to amend the Enbrel UPL rule on August 22, 2025, reflecting a proposed upper payment limit of $583.59 per unit. Defendants deny the remaining allegations in paragraph 74.

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.

Defendants' Response: Defendants admit that during its August 22, 2025, deliberations regarding the Enbrel UPL rule, the Board discussed the Maximum Fair Price for Enbrel that Amgen negotiated with the Centers for Medicare and Medicaid Services pursuant to the federal Inflation Reduction Act. Defendants deny the remaining allegations in paragraph 75.

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.

Defendants' Response: Defendants deny the allegations in paragraph 76.

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]

Defendants' Response: Defendants admit that during its August 22, 2025, deliberations regarding the Enbrel UPL rule, the Board discussed the Maximum Fair Price for Enbrel that Amgen negotiated with the Centers for Medicare and Medicaid Services pursuant to the federal Inflation Reduction Act. Defendants deny the remaining allegations in paragraph 77.

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

[19] Ex. I at 18.
[20] *Id.* at 41.

"round up" from the federal MFP in order to provide "wiggle room" in case the MFP changed.[21]

Defendants' Response: Defendants admit that the Board voted to adopt the Enbrel UPL rule on October 3, 2025, reflecting an upper payment limit of $600.00 per 50 milligrams/milliliter per unit. Defendants also admit that, during its October 3, 2025, deliberations regarding the Enbrel UPL rule, the Board discussed the Maximum Fair Price for Enbrel that Amgen negotiated with the Centers for Medicare and Medicaid Services pursuant to the federal Inflation Reduction Act. Defendants deny the remaining allegations in paragraph 78.

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

Defendants' Response: Defendants admit that, on October 3, 2025, the Board asked questions of people providing public comments and deliberated about the proposed Enbrel UPL rule. Defendants deny the remaining allegations in paragraph 79.

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

[21] Ex. J at 23, 37–38, 48.
[22] *Id.* at 82.

$600.00 per unit.[23] The upper payment limit will take effect on January 1, 2027. See Ex. A.

Defendants' Response: Defendants admit that the Board voted to adopt the Enbrel UPL rule on October 3, 2025, and that the rule is effective on January 1, 2027; the rule can be found at Ex. A of Plaintiffs' Complaint and refer to that rule for its contents. Defendants deny the remaining allegations in paragraph 80.

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.

Defendants' Response: Defendants refer to the Colorado Register, Volume 48, Number 21, published on November 10, 2025, at pages 1032-1034, for their contents. Defendants deny the remaining allegations in paragraph 81.

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.

Defendants' Response: Defendants deny the allegations in paragraph 82.

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

[23] *Id.* at 99–100.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants also admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants deny the remaining allegations in paragraph 83.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that the Board promulgated rules, which can be found at 3 Colo. Code Regs. § 702-9 *et seq*., and refer to those rules for their contents. Defendants also admit that they moved for summary judgment in *Amgen Inc. et al. v. Mizner et al.*, No. 24-cv-810 (D. Colo.), and refer to that case for its contents. Defendants deny the remaining allegations in paragraph 84.

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.

Defendants' Response: Defendants admit that Amgen sued Defendants in March 2024 in *Amgen Inc. et al. v. Mizner et al.*, No. 24-cv-810 (D. Colo.), and refer to that case for its contents.

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.

Defendants' Response: Defendants deny the allegations in paragraph 86.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 87, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 88, and therefore, deny them.

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

Defendants' Response: Defendants deny the allegations in paragraph 89.

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).

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants admit that hearings on SB 21-175 occurred before the Colorado House Health & Insurance Committee, the Senate Appropriations Committee, and the Senate Health & Human Services Committee, and refer to those hearings for their contents. Defendants deny the remaining allegations in paragraph 90.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 91.

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]

Defendants' Response: Defendants admit that on May 23, 2025, the Board deliberated regarding the Enbrel UPL rule. Defendants deny the remaining allegations in paragraph 92.

93. Similarly, at the May 23, 2025 hearing, a wholesaler representative on

[24] Ex. G at 56.
[25] Ex. J at 52.

the Board-appointed Advisory Council explained to Board members that if a wholesaler is required to sell a drug to "the downstream 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]

Defendants' Response: Defendants deny the allegations in paragraph 93.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 94, and therefore, deny them.

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,

[26] Ex. G at 59–60.

healthcare providers, and consumers about the UPL in advance of its effective date.[27]

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Amgen incurring costs in advance of the January 1, 2027, effective date, and therefore, deny them. Defendants admit that, during its October 3, 2025, deliberations regarding the Enbrel UPL rule, the Board discussed how it would communicate an upper payment limit to Colorado entities consistent with sections 10-16-1401 to 1416, C.R.S. Defendants deny the remaining allegations in paragraph 95.

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]

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 96.

97. Regardless of when the Board sends the inquiry letter, Amgen must

[27] Ex. J at 101.
[28] *Id.* at 102.

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.

Defendants' Response: Defendants admit that Colorado enacted SB 21-175 and HB 23-1225, and refer to those bills and statutes, specifically sections 10-16-1401 to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 97.

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, 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.").

Defendants' Response: Defendants admit Plaintiffs cite *Chamber of Com. v. Edmondson*, 594 F.3d 742 (10th Cir. 2010), and refer to that case for its contents. Defendants deny the remaining allegations in paragraph 98.

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).

Defendants' Response: Defendants admit Plaintiffs cite *Salomon & Ludwin, LLC v. Winters*, 150 F.4th 268 (4th Cir. 2025), and refer to that case for its contents. Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 99, and therefore, deny them.

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.

Defendants' Response: Defendants incorporate their responses to all other paragraphs above as if fully set forth 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.

Defendants' Response: Defendants admit that the U.S. Constitution states that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Defendants deny the remaining allegations in paragraph 101.

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)).

Defendants' Response: Defendants admit Plaintiffs cite *English v. Gen. Elec. Co.*, 496 U.S. 72 (1990), and *Biotech. Indus. Org. v. District of Columbia (BIO)*, 496 F.3d 1362 (Fed. Cir. 2007), and refer to those cases for their contents. Defendants deny the remaining allegations of paragraph 102.

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.

Defendants' Response: Defendants admit that the U.S. Constitution states that "[The Congress shall have Power . . .] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art I, § 8, cl. 8. Defendants also admit Plaintiffs cite *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), and *Biotech. Indus. Org. v. District of Columbia (BIO)*, 496 F.3d

1362 (Fed. Cir. 2007), and refer to those cases for their contents. Defendants deny the remaining allegations in paragraph 103.

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

Defendants' Response: Defendants deny the allegations of paragraph 104.

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.

Defendants' Response: Defendants deny the allegations of paragraph 105.

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.

Defendants' Response: Defendants deny the allegations of paragraph 106.

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.

Defendants' Response: Defendants deny the allegations of paragraph 107.

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

[29] Ex. C at C-9; Ex. D at C-11.
[30] Ex. J at 82.

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.

Defendants' Response: Defendants deny the allegations of paragraph 108.

109. Accordingly, the Act and its application to Enbrel implicate both field and conflict preemption and are preempted by the federal patent laws.

Defendants' Response: Defendants deny the allegations of paragraph 109.

Count 2
Violation of Due Process

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

Defendants' Response: Defendants incorporate their responses to all other paragraphs above as if fully set forth 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)."

Defendants' Response: Defendants admit that the U.S. Constitution states that no government shall "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV § 1. Defendants also admit Plaintiffs cite *Old*

Dearborn Distrib. Co. v. Seagram-Distillers Corp., 299 U.S. 183 (1936), and refer to that case for its contents. Defendants deny the remaining allegations of paragraph 111.

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 decision making and ensure that governmental officials are acting in the broader public interest and not for capricious or impermissible reasons.

Defendants' Response: Defendants deny the allegations of paragraph 112.

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.

Defendants' Response: Defendants deny the allegations of paragraph 113.

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.

Defendants' Response: Defendants deny the allegations of paragraph 114.

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

Defendants' Response: Defendants deny the allegations of paragraph 115.

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.

Defendants' Response: Defendants deny the allegations of paragraph 116.

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 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.

Defendants' Response: Defendants deny the allegations of paragraph 117.

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.

Defendants' Response: Defendants incorporate all their responses to other paragraphs above as if fully set forth 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)).

Defendants' Response: Defendants admit that the U.S. Constitution provides Congress with the power to "to regulate commerce with foreign nations, among states, and with the Indian tribes." U.S. Const. art. I, § 8, cl. 3. Defendants also admit Plaintiffs cite *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356 (2023), and refer to that case for its contents. Defendants deny the remaining allegations of paragraph 119.

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.").

Defendants' Response: Defendants deny the allegations of paragraph 120.

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.

Defendants' Response: Defendants admit that Colorado enacted SB21-175 and HB23-1225, and refer to those bills and statutes, specifically sections 10-16-1401

to 1416, C.R.S., for their contents. Defendants deny the remaining allegations in paragraph 121.

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).

Defendants' Response: Defendants deny the allegations of paragraph 122.

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).

Defendants' Response: Defendants deny the allegations of paragraph 123.

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.

Defendants' Response: Defendants deny the allegations of paragraph 124.

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).

Defendants' Response: Defendants deny the allegations of paragraph 125.

GENERAL DENIAL

Defendants deny each and every allegation contained in the Complaint not expressly admitted, and deny all averments contained in Plaintiffs' "Prayer for Relief" in the Complaint, including that Plaintiffs are entitled to the requested relief.

AFFIRMATIVE DEFENSES

1. Plaintiffs' claims are not justiciable.
2. Plaintiffs do not have standing.
3. The Court should abstain from hearing this suit under the *Burford* doctrine.
4. Plaintiffs fail to state a claim upon which relief may be granted.
5. Plaintiffs' claims fail because the regulatory regime does not violate the Supremacy Clause, the Due Process Clause, or the Commerce Clause.

DATED at Denver, Colorado this 16th day of January, 2026.

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