IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC.; et al.

Plaintiffs,

v.

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's ("Plaintiffs") Complaint [Doc. 1].

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about 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 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.

Defendants' Response: Defendants deny the allegations in paragraph 2 of the Complaint.

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:

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.[1]

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*.

Defendants' Response: Defendants deny the allegations in paragraph 4 of the Complaint.

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

[1] Plaintiffs also named the Colorado Prescription Drug Affordability Review Board (the "Board") in their Complaint but have since voluntarily dismissed the Board from the suit. [ECF #19].

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 5.

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*.

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 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.

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. 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.

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. 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.

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 violates the U.S. Constitution in at least four ways.

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

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.

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

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 of the Complaint.

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.[2]

Defendants' Response: Defendants admit that the Board issued a Policy document that states, "An upper payment limit does not apply to the purchase or

[2] 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.

reimbursement made by Medicare or non-participating self-funded health benefit plans," and refer to that Policy document for its contents. Defendants deny the remaining allegations in paragraph 13 of the Complaint, including the remaining allegations in footnote 1.

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

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

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

Defendants' Response: Defendants deny the allegations in paragraph 15 of the Complaint.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 16 and, therefore, deny them.

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.

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 17 and, therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 18 and, therefore, deny them.

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.

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 the Board has its principal office in Denver, Colorado. Defendants deny the remaining allegations in paragraph 19.

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.

Defendants' Response: Defendants admit the allegations in paragraph 20 of the Complaint.

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.

Defendants' Response: Defendants admit the allegations in paragraph 21 of the Complaint.

22. 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 the allegations in paragraph 22 of the Complaint.

23. 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 the allegations in paragraph 23 of the Complaint.

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.

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

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.

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 authority as a type 1 entity under state law. C.R.S. § 10-16-1402(1). Defendants deny the remaining allegations in paragraph 25.

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.

Defendants' Response: Defendants admit the allegations of paragraph 26 of the Complaint.

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.

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

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.

Defendants' Response: Defendants admit that Plaintiffs purport to invoke the jurisdiction of this Court. Defendants deny the remaining allegations in paragraph 28 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations in paragraph 29 of the Complaint.

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.

Defendants' Response: Defendants admit that Plaintiffs purport to invoke the venue of this Court. Defendants deny the remaining allegations in paragraph 30 of the Complaint.

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).

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 deny the remaining allegations in paragraph 31.

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.

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 deny the remaining allegations in paragraph 32 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 33 of the Complaint.

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 ….").

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 deny the remaining allegations in paragraph 34 of the Complaint.

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

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 35 and the articles referenced footnotes 2-4 and, therefore, deny them.

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 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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[3] 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.

[4] 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.

[5] 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 36 of the Complaint.

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).

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 37 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 38 of the Complaint.

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).

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 39.

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).

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 40.

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).

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. 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).

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. 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).

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 43.

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).

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 44.

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.

Defendants' Response: Defendants deny the allegations of paragraph 45 of the Complaint.

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).

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 46.

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).

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 47.

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).

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 48.

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).

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 49.

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.

Defendants' Response: Defendants admit that Enbrel was approved by the FDA in 1998 and is approved by the FDA 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 50 and, therefore, deny them.

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.

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 51 and, therefore, deny them.

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.

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 52 and, therefore, deny them.

53. 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 53, and therefore, deny them.

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.

Defendants' Response: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 54, and therefore, deny them.

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).

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 55, and therefore, deny them.

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.[6]

Defendants' Response: Defendants admit the allegations of paragraph 56 of the Complaint.

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.

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 57 of the Complaint.

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.

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 58 of the Complaint.

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[6] 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.

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.[7] 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."[8]

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 59 of the Complaint.

60. Further emphasizing Enbrel®'s patent protection, the report included an appendix section specifically devoted to the topic of "Patents and Exclusivity."[9] 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."[10] The

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

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."[11] 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.[12]

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 60 of the Complaint.

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"[13]—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).

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[11] *Id.* at C-11.
[12] *Id.*
[13] 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).

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 61.

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 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).

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 admit that

section 10-16-1407(5), C.R.S., states that the effective date of an upper payment limit established by the Board must be at least six months after adoption. Defendants deny that section 24-4-103(4)(d), C.R.S. requires rulemaking to take a maximum of 180 days and refer this court to that statute for its contents. Defendants deny the remaining allegations in paragraph 62.

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."[14] The final report was otherwise identical to the draft report in all relevant respects, including the discussion of Enbrel®'s patents.[15]

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 relied on by the Board in reaching its determination.. Defendants deny the remaining allegations in paragraph 63.

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

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

upper payment limit that will prevent Plaintiffs from realizing the full benefit of their federal patent exclusivity.

Defendants' Response: Defendants deny the allegations contained in paragraph 64 of the Complaint.

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

Defendants' Response: Defendants deny the allegations contained in paragraph 65 of the Complaint.

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.

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

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 any remaining allegations in paragraph 67 of the Complaint.

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)).

Defendants' Response: Defendants deny the allegations of paragraph 68 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 69 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 70 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 71 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 72 of the Complaint.

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."[16] 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 in paragraph 73 of the Complaint.

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

Defendants' Response: Defendants deny the allegations of paragraph 74 of the Complaint.

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

Count 2

Violation of Due Process

75. 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.

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®.

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 lack knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 76, and therefore, deny them.

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).

Defendants' Response: Defendants deny the allegations of paragraph 77 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 78 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 79 of the Complaint.

80. 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 80 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 81 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 82 of the Complaint.

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.

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

Defendants' Response: Defendants deny the allegations of paragraph 84 of the Complaint.

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).

Defendants' Response: Defendants deny the allegations of paragraph 85 of the Complaint.

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.

Defendants' Response: Defendants admit that laws governing Medicare are codified in Title 52 of the United States Code and refer to those statutes for their contents. Defendants deny the remaining allegations of paragraph 86 of the Complaint.

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.

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 19. Defendants deny the remaining allegations of paragraph 87 of the Complaint.

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).

Defendants' Response: Defendants deny the allegations of paragraph 88 of the Complaint.

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.

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

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 deny the remaining allegations of paragraph 90 of the Complaint.

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.").

Defendants' Response: Defendants deny the allegations of paragraph 91 of the Complaint.

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.

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 92.

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).

Defendants' Response: Defendants deny the allegations of paragraph 93 of the Complaint.

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.

Defendants' Response: Defendants deny the allegations of paragraph 94 of the Complaint.

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. Plaintiffs' claims are not ripe.
4. Plaintiffs' claims are moot.
5. The Court should abstain from hearing this suit under the *Burford* doctrine.
6. Plaintiffs fail to state a claim upon which relief may be granted.
7. 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 24th day of May, 2024.

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