UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

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

BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF AMICUS CURIAE[1]

The Biotechnology Innovation Organization ("BIO") is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO's members, which include Plaintiffs (referred to herein as "Amgen") and four other companies whose products were selected for affordability review in Colorado (Gilead, Janssen, Novartis, and Vertex), range from biotech start-ups to some of the world's largest biopharmaceutical companies. They are all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector.

In particular, BIO advocates for innovation in biotechnology in the healthcare space, to bring treatments and cures to patient populations in the U.S. and throughout the world. Biological medicines, which include Amgen's Enbrel, are now used to treat previously untreatable diseases and have prolonged and improved the lives of countless patients. However, development of a biological medicine generally requires a decade or more of research, as well as a fully capitalized investment that on average exceeds $2 billion.

[1] No party's counsel authored this brief in whole or in part, and no entity or person, other than *amicus*, its members, or its counsel, contributed money intended to fund the preparation or submission of this brief.

Colorado's Senate Bill 21-175, as amended by House Bill 23-1225 (collectively, the "PDAB Statute"), poses a direct threat to the Congressional policies as reflected in federal statutes that are essential to the development and dissemination of groundbreaking pharmaceutical treatments throughout the United States. Amicus BIO, reflecting the combined experience of its 1,000+ member companies, can assist the Court in understanding more fully the extent of the conflict between Colorado's PDAB Statute and federal law and regulations regarding innovation.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amgen's motion for preliminary injunction (the "Motion" or "Mot.") first focuses on the merits of Amgen's patent preemption claim, *see* Mot. at 25–30, which challenges Colorado's attempt to deprive drug manufacturers of the benefit of exclusivity rights granted to them by Congress as a way to encourage innovation in the pharmaceutical industry. That issue is of critical interest to BIO's members; indeed, BIO litigated the leading case in the area, which struck down a similar state effort to deprive pharmaceutical companies of the benefits of their patent rights by imposing price caps on sales of their medicines within the state. *See Biotech. Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007) (treating the District of Columbia as a state for preemption purposes).

Those federal policies would not cease to be relevant, nor would Colorado's law frustrate them any less if, as Colorado has previously argued, the PDAB Statute operates only on downstream sales. The market for pharmaceutical products in the United States operates to a very significant extent through wholesalers and distributors. Indeed, Colorado earlier acknowledged that substantially all of Amgen's

sales in the United States are to pharmaceutical wholesale distributors. If the mere fact that distribution of drugs and biologics takes place through middlemen were sufficient to defeat the manufacturer's exclusivity right to recoup their investment in developing that drug or biologic, states would be free to trample not only on patent rights, but the numerous other exclusivity rights that Congress has adopted with specific application to the life sciences industry.

ARGUMENT

I. Colorado's PDAB Statute Impermissibly Interferes with the Federal Policies and Framework of Encouraging Innovation in New Drugs and Biologics Through Exclusivity Rights.

Amgen is likely to succeed on the merits of its patent preemption claim. *See* Mot. at 25–30. Colorado's new price cap on Enbrel stands as a clear obstacle to the federal patent exclusivity to which Enbrel is entitled through 2029, the validity of which the Federal Circuit has expressly upheld. *See id.* at 9–10 (citing *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1068 (Fed. Cir. 2020), *cert. denied*, 141 S. Ct. 2623 (2021)).

In an earlier related litigation, Colorado relied upon the mistaken view that Amgen's patent rights are irrelevant to its lawsuit simply because Amgen first sells Enbrel to wholesalers and distributors outside of Colorado, even though that same Enbrel ultimately is dispensed to a patient in Colorado (and is thus squarely within the scope of the PDAB Statute). *See id.* at 29–30 (discussing Colorado's view). That view, if adopted by this Court, would eviscerate the numerous Congressionally mandated exclusivity rights, including both patent rights and many others, that Congress has specifically conferred on biotechnology and pharmaceutical companies

in order to incentivize their innovation of new medical therapies. As the Federal Circuit recognized in the seminal *BIO* case, federal patent law preempts state caps on the prices of patented drugs, because doing so "diminish[es] the reward to patentees" in order to "provide greater benefit to [in-state] drug customers." 496 F.3d at 1374.

Further, the reality is that the vast majority of drugs and biologics, including Amgen's Enbrel, are distributed through wholesalers and distributors. Thus, if Colorado's view were adopted, Colorado and every state would be free to deprive pharmaceutical and biotechnology companies of the benefit of their patent and other exclusivity protections by simply being explicit that it is only capping the price at which the drugs could be *re*-sold to in-state drug customers. But federal law preempts state laws that frustrate federal law *indirectly* as well as those that do so *directly*; as Amgen notes in its Motion, "state price controls obstruct the 'fundamental purpose' of Congress's grant of exclusive patent rights, which is to incentivize innovation by allowing manufacturers to set their own prices during the patent term." Mot. at 25 (quoting *BIO*, 496 F.3d at 1372).

Moreover, the numerous regulatory exclusivities that Congress has created specifically for pharmaceutical and biotechnology companies reflect that Congress was focused on creating *genuine* incentives for biotechnology innovation, not ephemeral rights that states could easily circumvent through clever draftsmanship. *Cf. Haywood v. Drown*, 556 U.S. 729, 742 (2009) ("[T]he Supremacy Clause cannot be evaded by formalism."). Indeed, Congress has employed exclusivity rights far more

broadly than just "patents" in the life sciences space, reflecting Congress's recognition that periods of exclusivity are *essential* to drive the innovation that has produced breakthrough treatments in the United States over the past several decades. Because of these policies and overall framework, the United States has been the global leader in critical new developments in the life sciences space.

As the U.S. Food and Drug Administration ("FDA") recognizes, while patents are a "property right" granted by the U.S. Patent and Trademark Office, regulatory exclusivities in the life sciences space go beyond generally applicable patent rights. Such regulatory exclusivities "refer[] to certain delays and prohibitions on approval of competitor drugs" that ensure the manufacturer will have the opportunity to market its product free of certain types of competition. *Frequently Asked Questions on Patents and Exclusivity*, Food and Drug Administration, https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity. The FDA's website lists no fewer than *seven* different types of regulatory exclusivities, in addition to patent rights, that Congress has provided to incentivize drug and biologic innovation. These include:

- **Orphan Drug Exclusivity** (ODE) – 7 years
- **New Chemical Entity Exclusivity** (NCE) – 5 years
- **Generating Antibiotic Incentives Now (GAIN) Exclusivity** – 5 years added to certain exclusivities
- **New Clinical Investigation Exclusivity** – 3 years
- **Pediatric Exclusivity** (PED) – 6 months added to existing Patents/Exclusivity
- **Patent Challenge** (PC) – 180 days . . .
- **Competitive Generic Therapy** (CGT) – 180 days . . .

Id. (citing 21 C.F.R. §§ 314.108, 316.31, 316.34 and §§ 505A, 505E, 505(j)(5)(B)(iv), 505(j)(5)(B)(v) of the Food, Drug, and Cosmetic Act). *See also, e,g.*, *Baker Norton Pharm., Inc. v. FDA*, 132 F. Supp. 2d 30, 31 (D.D.C. 2001) (citing 21 U.S.C. § 360cc(a)) (characterizing the seven-year "market exclusivity" conferred by orphan drug designation/approval as a "non-patent" exclusivity).

The Colorado PDAB scheme would not only defeat Congress's innovative purposes with respect to patent rights, but all of these regulatory exclusivities as well. If Colorado (and every state) is free to deprive a patent holder of its right to price its patented drug free of state law mandates simply by making the law apply as a technical matter to the wholesaler's resale of the product into the state, then Colorado can deprive manufacturers of the incentives provided by these other federal provisions as well. It matters not whether Colorado *has* gone after these other regulatory exclusivities *yet*; by the logic of Colorado's argument, it (and every state) *could* do so under state statutes like the PDAB Statute.

The example of federal orphan drug exclusivity is particularly apposite. Indeed, Colorado amended its PDAB Statute to include "orphan drug status" as one of the factors for the PDAB to consider in evaluating whether a drug is affordable. Congress enacted the Orphan Drug Act ("ODA") in 1983, and the Hatch-Waxman Act ("HWA") in 1984, to provide manufacturers with limited periods of market exclusivity for drugs that treat rare diseases and conditions. During the ODA period of market exclusivity, the FDA may not approve another application for the same drug for the same disease or condition. *See* 21 U.S.C. § 360cc(a). And during the HWA period of

market exclusivity, the FDA cannot approve generics of the protected drug. *See* 21 U.S.C. § 355(j)(5)(F)(ii).

In enacting the ODA and HWA, Congress enabled manufacturers to recoup the high costs of developing these novel compounds notwithstanding the conditions' smaller patient populations. Without the ODA and HWA, manufacturers would have little to no incentive to develop orphan drugs, given that such drugs treat diseases affecting fewer than 200,000 people in the United States. Even though orphan drugs can dramatically improve patient welfare and even save lives, their demand is small compared to their extremely high research-and-development costs. The ODA and HWA solve this problem by enabling manufacturers to recoup their high development costs through Congressionally mandated regulatory exclusivity periods in which prices can be determined free from certain forms of competition. Specifically, in the ODA, Congress aimed to "facilitate the development of drugs for rare diseases or conditions" because it found that, without this additional financial incentive, "it [was] not financially feasible, except as a public service, for a pharmaceutical manufacturer to expend research and development funds on drugs for these rare diseases or conditions." H.R. Rep. 97-840, at 6 (1982). Similarly, with the HWA, Congress sought to "create a new incentive for increased expenditures for research and development" of new drugs. H.R. Rep. 98-857, pt. 1, at 15 (1984).

Colorado's PDAB Statute lists "orphan drug status" as a factor in assessing affordability, without giving any indication as to which direction that consideration should weigh in the analysis; it simply lists such status as a factor in the affordability

review without further explanation. *See* Colo. Rev. Stat. § 10-16-1406(4)(g). One could easily imagine the Colorado PDAB reaching the conclusion that the very exclusivity that Congress has provided orphan drugs has led to the price being unaffordable for patients with rare diseases. The Colorado law appears to permit the Board to consider this exclusivity right as a factor *in favor* of subjecting the drug to affordability review and potential price caps under state law. *See id*. § 10-16-1406(2)(e).

The Generating Antibiotic Incentives Now ("GAIN") Act, enacted in 2012 as part of the Food and Drug Safety and Innovation Act, provides another example of the conflict between Colorado's arguments and the policies embodied in federal law. Concerned with the "public health threat of antibacterial drug resistance," Congress passed the GAIN Act to "stimulat[e] the development and approval of new antibacterial . . . drugs" by providing an exclusivity *extension* of five years that could even be added onto other exclusivities. *Report to Congress on Generating Antibiotic Incentives Now*, Food and Drug Administration (Aug. 29, 2017), https://www.fda.gov/files/about%20fda/published/Report-to-Congress-on-Generating-Antibiotic-Incentives-Now-%28GAIN%29.pdf. Under Colorado's scheme, the Colorado PDAB would be free to undermine such an exclusivity by imposing an upper payment limit ("UPL") on the resale of those new antibacterial products by wholesalers and distributors, even though doing so would reduce manufacturers' incentive to invest in and develop such critical drugs and thereby frustrate Congress's intent in the GAIN Act. Again, it does not matter that Colorado has not *yet* selected

such a drug for a UPL—it *could* do so per the PDAB Statute. If Colorado prevails in its arguments with respect to Enbrel, manufacturers would need to take serious pause before making such investments in the future because they could not know if states would try to counteract the benefits of Congressionally mandated regulatory exclusivity, and those companies may make the quite logical decision not to innovate. The federal government would thus lose a major tool in addressing other critical public health threats through similar legislation.

"[W]hen federal and state laws collide, the Constitution is clear: Federal law wins." *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1187 (10th Cir. 2023). A state law is "preempted when it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Standing Akimbo, LLC v. United States*, 955 F.3d 1146, 1165-66 (10th Cir. 2020) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Colorado's PDAB Statute reflects the mistaken position that states may freely engage in broad activities preempted not only by federal patent law but all other federal prescription drug exclusivity programs that Congress explicitly enacted to balance access with innovation. The statute therefore cannot stand. *See BIO*, 496 F.3d at 1374 (striking down D.C. law that "[b]y penalizing high prices . . . chose[] to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs" and therefore stood "as an obstacle to the federal . . . balance of objectives as established by Congress"); Mot. at 26–27 (discussing same).

CONCLUSION

For the foregoing reasons, and for the reasons set forth in Amgen's briefing, this Court should grant Amgen's Motion for Preliminary Injunction.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2025, I electronically filed the foregoing Amicus Brief with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to attorneys of record.

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