IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Daniel D. Domenico

Civil Action No. 1:25-cv-03452-DDD-STV

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

Plaintiffs,

v.

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

Defendants.

ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

The Colorado Prescription Drug Affordability Review Board was created to control the price of certain drugs for Colorado consumers. Doc.

45 at 4.[1] Amgen is a pharmaceutical company that makes Enbrel, a drug of substantial value to Colorado patients suffering from rheumatoid arthritis. Doc. 1 at 3. The Board seeks to cap its price. *Id.* at 28. Amgen objects.[2] Amgen argues that Colorado's price cap is preempted by federal patent law, violates its due process rights, and violates the commerce clause. *Id.* at 6-7. Amgen has moved for a preliminary injunction. Doc. 18. For the reasons below, the motion is granted.

BACKGROUND

The pharmaceutical pricing structure is, as the Board argues, rather opaque. Amgen sets a wholesale acquisition cost price at which it sells Enbrel to its wholesalers and distributors. Doc. 18 at 17. Rather than add a markup to this price, the wholesalers and distributors sell to pharmacies at this wholesale rate or below and receive reimbursement from Amgen for sales under the wholesale rate, known as a chargeback. *Id.* Though there are additional wrinkles to the pricing system, it suffices for our purposes to say that this wholesale rate is also the basis for whether a drug is subject to Colorado's regulatory regime. 3 Colo. Code Regs. § 702-9:3.1(C). Once a drug is determined to be eligible for board regulation, the Board determines whether it is "unaffordable" and if so, it can set a price cap. Colo. Rev. Stat. § 10-16-1407(1). The Board is given a non-exhaustive list of factors to consider in their determination of

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[1] Defendants are sued in their official capacity as members of the Board, Commissioner of the Colorado Division of Insurance, and Attorney General of Colorado. The latter two roles involve statutory requirements involving written notice for withdrawing distribution of a drug from the Colorado market and legal enforcement on behalf the board.

[2] This is the second time Amgen brings this objection to this Court. Its first case was dismissed for lack of standing as the Board had not yet set a price cap. *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. Mar. 28, 2025), ECF 49. The Board issued a cap and gave Amgen standing for this suit.

whether to cap a drug's price and has issued regulations with additional factors it considers. Colo. Rev. Stat. § 10-16-1406(4); 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). The statutory factors include cost, availability of alternatives, and effects on consumer access to a drug. *Id*. The additional regulatory factors include evaluation of the wholesale cost and rebate system along with health equity factors. 3 Colo. Code Regs. § 702-9:3.1(E)(2)(j). Most of these factors are laid out as overarching categories for consideration.

The Board determined that Enbrel qualified for a price cap and set the cap approximately 70% below Amgen's wholesale price. Doc. 18 at 22. Amgen sued, alleging the Boards determination is preempted by federal patent law, violative of its Due Process rights, and contrary to the dormant Commerce Clause. It moves for a preliminary injunction on the first two claims.

LEGAL STANDARD

The standard for assessing a motion for a preliminary injunction is governed by Tenth Circuit law. "A preliminary injunction is an extraordinary remedy, the exception rather than the rule." *Mrs. Fields Franchising, LLC v. MFGPC*, 941 F.3d 1221, 1232 (10th Cir. 2019). One may be granted "only when the movant' s right to relief is clear and unequivocal." *McDonnell v. City & Cnty. of Denver*, 878 F.3d 1247, 1257 (10th Cir. 2018). To succeed on a motion for preliminary injunction, the moving party must show: (1) that it is "substantially likely to succeed on the merits" ; (2) that it will "suffer irreparable injury" if the court denies the injunction; (3) that its "threatened injury" without the injunction outweighs the opposing party' s under the injunction; and (4) that the injunction is not "adverse to the public interest." *Mrs. Fields*, 941 F.3d at 1232; *accord Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

On the other hand, while federal district courts have jurisdiction to hear claims arising from patents under 28 U.S.C. § 1338, including preemption claims, precedent from the Federal Circuit controls the substance of the inquiry. *Biotech. Indus. Org. v. District of Columbia* (*BIO I*), 496 F.3d 1362, 1369 (Fed. Cir. 2007).

DISCUSSION

Both parties make important, and persuasive, policy arguments: Colorado is undoubtedly correct that the price of many beneficial medications is difficult, if not impossible, for many citizens to afford. Amgen is correct that the development of the new medications many of us benefit from requires that profits from the few successful ones be large enough to cover not only their own development, but that of dozens of failed experiments. Ultimately, however, those policy issues are not relevant to the legal decision here. Since under binding Federal Circuit precedent, caps on the price of patented drugs like Enbrel are preempted by federal law, Amgen's motion must be granted.[3]

The Board's main argument is that Amgen has not shown that it will actually be harmed by the price cap given the convoluted way Enbrel is paid for at various levels of the supply chain. And they are right that the system is convoluted, confusing, and often counterintuitive. But it is not necessary to unravel the entire system to understand that, as a result of Colorado's cap, Amgen will receive less money from its wholesalers and will fare more poorly in negotiations with other purchasers in Colorado and elsewhere. The Board attempts to minimize these losses, pointing out that the cap does not apply to sales made by Amgen itself, and that some sales, such as to ERISA plans, are not controlled by Colorado law.

[3] It is therefore not necessary to reach Amgen's alternative Due Process argument.

Doc. 54 at 8. While possibly true, this is an argument about the scope of damages, not their existence. As a matter of basic economic logic, Amgen is likely to be significantly harmed by a cap on the price of its product, even if the cap applies unevenly and down the chain. That is sufficient to satisfy its burden.

I. Likelihood of success on the merits

The Federal Circuit's decision in *Biotech Industry Organization* controls the outcome here. *Bio I*, 496 F.3d 1362. In that case, the plaintiff challenged the District of Columbia's Prescription Drug Excessive Pricing Act, which banned pharmaceutical pricing it deemed excessive. *Id.* at 1365. Excessive pricing was established relative to drug pricing in other countries. *Id.* The Federal Circuit held that the District's price caps were preempted by federal patent laws. *Id.* at 1374.

In doing so, the court explained that Congress recognizes that enhanced profits are central to the statutory incentives involved in patents. *Id.* These enhanced profits are only enjoyed by pharmaceutical companies during the period of patent exclusivity before competition brings the price down.[4] The Federal Circuit recognized that this is in tension with the desire to keep prices low, but balancing these two competing interests, "to reward innovators with higher profits and to keep prices reasonable for consumers," was the responsibility of Congress. *Id.* And it held that the "underlying determination about the proper balance

[4] The Board argues that the Patent Act guaranties no particular price, citing *Impression Prods., Inc. v. Lexmark Int'l, Inc., 581 U.S. 360, 380 (2017)*. Doc. 54 at 31. True, but the question is whether state law "must yield to congressional enactments if it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Bio I*, 496 U.S. at 1372 (*citing Leatherman Tool Group, Inc. v. Cooper Indus., Inc.,* 131 F.3d 1011, 1015 (Fed.Cir.1997). The Federal Circuit's answer is that it must.

between innovators' profit and consumer access to medications, thought, is exclusively one for Congress to make." *Id.* The District's efforts to alter that balance in one direction was therefore preempted. *Id.* at 1374.

The District of Columbia's petition for rehearing en banc was denied with a concurrence and dissent. *Biotech. Indus. Org. v. District of Columbia* (*BIO II*), 505 F.3d 1343 (Fed. Cir. 2007). The concurrence noted that "there is a particularly acute tension in the pharmaceutical context between promoting innovation by increasing the profit reward of patents and the public interest in affordable drugs," which was the precise subject of the Hatch-Waxman Act, which extended the patent term for pharmaceuticals and simplified the generic drug approval process. 505 F.3d at 1347 (Gajarsa, J., concurring in denial of rehearing en banc). The dissent thought that the decision in *Bio I* was errant because it found "a conflict between the D.C. Act and a supposed polity of the patens law to allow patent holders to reap maximum profits during the term of the limited monopoly on the use of the invention." *Id.* at 1350 (Dyk, J., dissenting from denial of rehearing en banc). Each opinion confirms the appropriate read of the Federal Circuit's controlling precedent: that Colorado's attempt to rebalance Congress's patent system is preempted by federal law.

The Board concedes that these precedents are binding but attempts to distinguish the situation. It argues that Amgen is not the real object of its regulation. It claims that the doctrine of patent exhaustion puts Amgen outside the scope of the regulation. Doc. 54 at 35-36. But this distinction does not make a difference. Just as in this case, the District of Columbia's law did "not directly regulate manufacturers' wholesale prices." *Id.* at 1371. Once a patent holder has sold an item, it has no more rights secured by the patent monopoly. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 371 (2017). But that case dealt with

whether a patentee could control purchaser behavior beyond the first sale. *Id*. at 372. The Court pointed to the common law's refusal to permit restraints on the alienation of chattels. *Id*. at 371. And were Amgen suing its wholesalers, that would be apt. The question here is whether a state may, by capping downstream prices, change the bargain struck by Congress. *See Bio I*, 496 F.3d at 1373. The Federal Circuit held that federal patent law means it cannot. Amgen is substantially likely to succeed on the merits of its preemption claim.

II. Irreparable harm

The puzzling opacity of the pharmaceutical pricing system also bears on whether Amgen will suffer irreparable harm if I do not grant issue a preliminary injunction. Amgen must demonstrate that there is a significant risk that it cannot be compensated after the fact by monetary damages. *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003). More than the possibility of some remote future injury is required. *Winter*, *Winter v. Nat. Res. Def. Council, Inc.,* 555 U.S. 7, 22 (2009) (quoting 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948.1).

The Board argues that Amgen's has not provided empirical evidence that it will actually be harmed by the price cap. First, there is significant evidence on that point in the record. *See, e.g.*, Doc. 25 at 3. Even if there weren't, basic economic logic confirms Amgen's core contention. The point of the Board's price cap, of course, is to lower the price that can be charged for Enbrel, and the Board expects it to have that effect. And if the end price is capped below what the market will bear, at least some of the reduced income will come out of Amgen's pocket. Such an economic injury caused by governmental action that changes market conditions is sufficient to establish injury. *Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319 (Fed. Cir. 2009) (*citing Clinton v. City of*

New York, 524 U.S. 417, 433 (1998)). Caselaw confirms the commonsense proposition that a law can be "aimed directly at" a plaintiff as a targeted object, *American Booksellers Ass*'n, 484 U.S. at 392, even if it does not directly regulate his actions. *Energy Future Coal. v. EPA*, 793 F.3d 141, 144 (D.C. Cir. 2015) (Kavanaugh, J.). As the Supreme Court has explained, "when the government regulates (or under-regulates) a business, the regulation (or lack thereof) may cause downstream or upstream economic injuries to others in the chain, such as certain manufacturers, retailers, suppliers, competitors, or customers." *FDA v. Alliance for Hippocratic Medicine*, 602 U. S. 367, 384 (2024).

Amgen also argues that negotiations with its wholesalers and distributors have already begun for 2027 contracts for Enbrel. Doc. 18 at 43. These negotiations, it alleges, ordinarily conclude around May. *Id*. It takes no great imaginative leap to conclude that the people sitting across the table from Amgen will conclude that a capped price for a substantial portion of Colorado's insured patients will drive down Amgen's negotiating position and the negotiated price of Enbrel with it. Amgen also argues that it has existing contracts that run into 2027 that cannot be easily renegotiated. *Id*. at 44. Add to this that Colorado law requires Amgen to decide whether to withdraw from the Colorado market by July 5, 2026 or sell Enbrel at the capped price. *Id*.

Amgen will already spend part of 2027 operating under a contract negotiated before Colorado's price cap was contemplated. And it will need to finalize the rest of its contracts without knowing how severely its wholesale prices will be affected. Each is certain enough to qualify as irreparable harm. These damages will prove quite difficult to calculate. The Board characterizes Amgen's damages as too speculative to warrant an injunction when they are actually too speculative to calculate after

the fact. *See Southwest Stainless, LP v. Sappington*, 582 F.3d 1176 (10th Cir. 2009).

The Board suggests that any harms could be redressed by suits after the fact for a regulatory taking. Doc. 54 at 29. Amgen points out, however, that the Board possesses sovereign immunity against suits for damages. If Amgen prevails, the Board may well assert this immunity to avoid paying the judgment as it indicated at oral argument. And at the hearing on this motion, Colorado, for obvious reasons, would not concede Amgen's likelihood of success in state court on such a claim, even if Amgen prevailed in this Court. The theoretical possibility of a separate lawsuit that all parties recognize would be quite unlikely to prevail does not make Amgen's harm redressable.

III. Balance of Equities and Public Interest

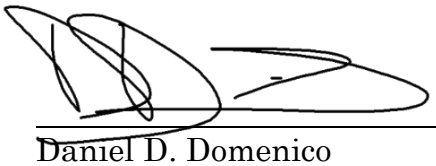
As to the balance of equities and the public interest, these factors "merge" when the government is the party opposing the injunction. *Nken v. Holder*, 556 U.S. 418, 435 (2009). But where a law is likely unconstitutional, the interests of the government "do not outweigh" the plaintiff's interest in having its constitutional rights protected. *Awad v. Ziriax*, 670 F.3d 1111, 1131 (10th Cir. 2012). This principle applies where the alleged constitutional infirmity is preemption. *Chamber of Com. v. Edmondson*, 594 F.3d 742, 771 (10th Cir. 2010). The state's interest in helping citizens afford Enbrel is legitimate, and it has a number of ways to try to do so, including subsidization, using its market power to negotiate lower prices as the federal government has done, or perhaps by finding ways to encourage simplification of the puzzling supply chain. But one way it cannot do so under the binding precedent of the Federal Circuit, is by capping the price of a patented drug.

CONCLUSION

It is ORDERED that:

The MOTION FOR PRELIMINARY INJUNCTION (Doc. 18) is GRANTED. Defendants are enjoined from enforcing the upper payment limit for Enbrel.

DATED: July 1, 2026 BY THE COURT:



Daniel D. Domenico
Chief United States District Judge