UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

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

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

Plaintiffs,

v.

GAIL MIZNER, MD, in her official capacity,
SAMI DIAB, MD, in his official capacity,
AMARYLIS GUTIERREZ, PharmD, in her official capacity,
CATHERINE HARSHBARGER, in her official capacity,
JAMES JUSTIN VANDENBERG, PharmD, in his official capacity,
MICHAEL CONWAY, in his official capacity, and
PHILIP WEISER, in his official capacity,

Defendants.

REPORTER'S TRANSCRIPT
(Motions Hearing)

Proceedings before the HONORABLE NINA Y. WANG, Judge, United States District Court, for the District of Colorado, commencing at 10:02 a.m. on the 22nd day of October, 2024, Alfred A. Arraj United States Courthouse, Denver, Colorado.

A P P E A R A N C E S

FOR THE PLAINTIFF:
PAUL ALESSIO MEZZINA, King & Spalding LLP, 1700 Pennsylvania Avenue NW, Suite 900, Washington, DC 20006

CLIFF STRICKLIN, King & Spalding LLP, 1401 Lawrence Street Suite 1900, Denver, CO 80202

FOR THE DEFENDANT:
ABBY L. CHESTNUT, HEATHER SUZANNE FLANNERY, RUSSELL DORIAN JOHNSON, and PAWAN NELSON, Colorado Department of Law, Ralph L. Carr Colorado Judicial Center, 1300 Broadway, Denver, CO 80203

OCTOBER 22, 2024

(Proceedings commence at 10:02 a.m.)

THE COURT: Thank you. Please be seated.

On the record in 24-cv-810-NYW, Amgen, Inc., et al versus Mizner, et al.

Could I have appearances of counsel, please.

MR. MEZZINA: Good morning, Your Honor, Paul Mezzina for the Amgen plaintiffs. I am here with my colleague, Cliff Stricklin.

MR. STRICKLIN: Good morning.

MR. MEZZINA: And our client representative, Melissa Pastrana.

MS. PASTRANA: Good morning.

MS. CHESTNUT: Good morning, Your Honor, Abby Chestnut for the defendants, and I am joined by counsel Russell Johnson, Heather Flannery, and Pawan Nelson.

THE COURT: Good morning.

All right. We are here for a motions hearing on the cross motions for summary judgment, Docket Entry No. 24 and Docket Entry No. 29. Probably what is the easiest thing to do is to allow the plaintiffs to argue first, then the defendants may respond, and plaintiffs can reply, then defendants, if there is anything left to say, can have the last word.

All right. So I have been through your papers, so

just keep that in mind. And I may be interrupting you all for some questions. All right. When you are ready.

MR. MEZZINA: Thank you, Your Honor. May I go to the podium?

Thank you. May it please the Court. As Your Honor knows, the Federal Circuit is the controlling decision in *Bio v. District of Columbia.* States cannot impose price controls on patented drugs because doing so interferes with the incentives for innovation that Congress set creating the patent laws.

THE COURT: So I am going to stop you even before you get into patent issues, Mr. Mezzina, because I want to talk to you about the Court's authority in this case. As you know, this Court can't do anything unless it has subject matter jurisdiction. So I want you to address the standing issue, because before I can reach any substantive merits of each of the counts, I need to satisfy myself that this Court has standing with respect to each and every individual claim that is being asserted.

MR. MEZZINA: Certainly, Your Honor, I am happy to start with standing.

So the State's argument on standing, which is, you know, essentially the same argument that they make on the merits of a number of the claims, is that the price control that they are proposing to impose on Amgen's

patented drug Enbrel would not apply to Amgen's direct sales of Enbrel, instead it would apply to sales made by Amgen's wholesale and distributor partners.

THE COURT: And at this point you don't even know whether or not there is going to be a price restriction, do you?

MR. MEZZINA: So, Your Honor, let me address where we are in the proceedings. So the Board has taken two votes at this point. First it took a formal vote to find that Enbrel is unaffordable for Colorado consumers. That vote meant, under the statute, that Enbrel was eligible to have an improper payment limit or a price cap imposed.

THE COURT: Correct.

MR. MEZZINA: The Board then took a second vote to select Enbrel for establishment of an upper payment limit. So that vote essentially said, we are going to impose a UPL on Enbrel, and you now are going to have a minimum of three hearings to decide the amount of that UPL.

Now the State says, I think correctly, that it is not absolutely certain that those proceedings will end with a UPL. There is theoretical possibility that the Board could say, you know what, despite having found Enbrel unaffordable, we are going to go ahead and not impose any UPL. But no one has suggested that that is remotely likely or even offer any reason why that might

happen.

THE COURT: Right. But the plaintiffs in this case bear the burden of establishing standing; correct?

MR. MEZZINA: That's right, Your Honor. We think we have more than met that burden.

THE COURT: Isn't it speculative at this point if there is even a remote possibility that the UPL won't be imposed or what that UPL might be?

MR. MEZZINA: Well, Your Honor, respectfully, I don't think a remote or theoretic possibility that the harm might not come to pass is enough to defeat standing. The standard under *Susan B. Anthony List* is a substantial risk that we will face harm from this statute. Or, as Federal Circuit but it in *Bio*, a realistic danger that we will be injured.

We have far more than a substantial risk here where the Board has taken these two formal votes, set out down this path, it is clearly preparing to impose a UPL. We are farther along in the proceedings than the plaintiffs were in the *Bio* case. So, Your Honor, you may recall in the *Bio* case there was D.C. statute, but there had been no proceedings initiated under the statute as to any drug. There had been no determinations, even a preliminary determination, that any drug had an excessive price in the district.

So here we are quite a bit -- we are several steps farther down the road toward a UPL than was the case in *Bio*.

THE COURT: Okay.

MR. MEZZINA: So I think that that speaks to the constitutional standing question based on where we are in the proceedings and what we think is a very strong likelihood that these proceedings are going to end in a UPL.

I understand the State not to have really disputed that we have a sufficient risk of facing a UPL to have standing. They have framed their arguments in term of prudential ripeness. So I think the first thing I want to note about that is that prudential ripeness is a disfavored doctrine. A number of judges on the Tenth Circuit have suggested that it may no longer be good law. The Supreme Court has said unanimously that its continuing vitality is in question in light of the court's many recent statements that district courts have a virtually unflagging obligation to exercise jurisdiction in cases before them.

So that is where we start out on prudential ripeness. Now, we think the doctrine is a given. There are two factors that are relevant to prudential ripeness; the fitness of the issues for judicial decision and

hardship to the parties from delaying a decision.

The fitness of the issues primarily turns on whether they are purely legal or whether they require additional factual development to frame up the issues for the Court. In this case, the parties agreed in the joint motion at the start of the case that the issues presented by our claims are purely legal, it's ripe, preemption is a legal question, and there is no additional factual development that would help the Court to evaluate the merits of our claims.

As to hardship, we cited a number of cases that hold that when a state is undertaking an administrative process to decide whether to take an action that would be preempted, the process itself is the relevant burden, it is the hardship. The process imposes costs, it imposes uncertainty on Amgen. And we cited cases -- a number of cases from the preemption context where a state was pursuing an administrative appeals process to potentially take some action that was alleged to be preempted by federal patent law, like invalidating a federal patent contract, and in each of those cases, the Court held that ripeness does not require the court to wait for the eventual outcome of the state proceedings, the process itself is the preemptive burden, so the claim is ripe at the outset. And the State of Colorado has not responded

to those cases and not disputed what they hold.

The final point I want to make about ripeness, Your Honor, is that I think this is a prudential -- it is supposed to be practical, and as a practical matter, it is in everyone's interest to have a judicial ruling on the constitutionality of this statute as soon as possible before the Board and all of the stakeholders expend substantial additional time and resources on this process that we contend is fully preempted.

This Court made a similar observation in the *sPower* case; that really it is in all parties' interest to have this kind of preemption issue resolved before there is a lot of state and party resources spent on the preemptive process.

And, of course, if we were wait for the UPL to actually be imposed, we would just be right back here litigating the same issues again with no change in the relevant context, and it would just be on a much more compressed time frame, because there is only a six-month period between the setting of the UPL and when it takes effect. And so that's not a lot of time to complete both proceedings in this court, and presumably whichever party is unhappy with the decision, is going to take an appeal to the Federal Circuit, and that is a lot to get done in six months. So I really think it is practical and in

everyone's interest to proceed to a decision now.

So let me turn back to the downstream question. So what I understand to be the State's primary argument on standing is that the price cap would not apply to Amgen's own sales to its wholesalers and distributors, but it would apply at one step removed, to the sales that wholesalers and distributors make to pharmacies and healthcare providers.

Now, as an initial matter, that limitation on the application of the UPL is not found anywhere in the statute. The statute says in two different provisions, Section 1401(23) says the UPL applies to any financial transaction involving the drug. And Section 1407(5) says it applies to all purchases of the drug.

So there is no --

THE COURT: Those are only transactions occurring in Colorado; correct?

MR. MEZZINA: Well, so the way the statute is phrased is any financial transaction involving a drug that is dispensed or distributed in Colorado. So, as Your Honor knows on the commerce clause claim, we read that language to mean even transactions outside of Colorado, if the drug is later dispensed or distributed in Colorado as it makes its way --

THE COURT: That is subject to a different argument

by defendants.

MR. MEZZINA: That's right. That's right.

THE COURT: Okay.

MR. MEZZINA: The point I am making here is that there is no limitation in the statute that says this doesn't apply to Amgen's own sales, it only applies to wholesaler and distributor sales.

But even taking that limitation as a given, there are three reasons why it does not affect Amgen's standing. So the first is just basic economics and common sense. You know, we cite a number of cases where the court says you can rely on common sense and basic economics to establish standing.

Here, I think it's very clear that if you limit what a wholesaler or distributor can sell the drug for downstream, that limits what the wholesaler is going to be willing to pay to Amgen for the drug upstream. But here we don't even have to rely on just economic and common sense, because we have the unrebutted declaration of Patrick Costello in the record. And Mr. Costello explains at length how the supply chain works in the pharmaceutical industry and for Amgen specifically.

He says what is normal in this industry is that the manufacturer sells to its wholesalers and distributors at what is called WAC, the wholesale acquisition cost, and we

think it is also called the manufacturers list price. And then the wholesaler turns around and sells the drugs to the purchaser, either at WAC or at a price lower than WAC that incorporates some sort of purchase discount. And if a discount is required from the purchase, the manufacturer is obligated to reimburse the wholesaler for that discount; that is both as a matter of industry standard practice and also as a matter of what is required under Amgen's existing contracts with its wholesalers.

So any UPL that is imposed on a wholesaler would inevitably be borne by Amgen, because if that wholesaler has to provide a discount of the purchase based on the UPL, Amgen is then obligated to reimburse the wholesaler for the difference in price.

And the third point is the Colorado legislature knew it intended that this is how the statute would work. So if you look at the legislative history, the State, in its brief, cites a statement from one of the sponsors of the legislation who acknowledges exactly this reality. He says, we know how this industry works. If the wholesaler has to sell at a lower UPL, they will be made whole on the back end by the pharmaceutical manufacturer.

That was the intent, and it is also reflected in the statute, itself. For example, there are a number of provisions in the statute that contemplate that the drug

manufacturer may choose to withdraw the drug from the Colorado market based on the UPL, in particular Section 1407(10). And I should say parenthetically, Your Honor, when I cite statutes, these are all Colorado Revised Statute 10-16- the number that I am giving.

So the provision that I just cited required the Board to inquire of manufacturers whether they will continue to make the drug available for sale in Colorado given the UPL. They permit expedited review at the request of a patient if the drug is not going to be available because of the UPL, and impose a penalty on manufacturers who withdraw the drug from the Colorado market without sufficient notice because of the UPL.

So none of these provisions would make sense if the legislature didn't understand, as it clearly did, that the burden of the UPL was going to fall on the manufacturer. So, again, the relevant standard for standing is substantial risk or realistic danger, and we think we far exceed that in light of the record here.

So unless Your Honor has more questions about the threshold and jurisdictional issues, I will turn to patent preemption.

THE COURT: That's fine, thank you.

MR. MEZZINA: So, Your Honor, as I started out saying, we think the *Bio* decision is controlling. The

question that this case presents is whether states have to follow that decision or whether they can effectively nullify it by imposing a price cap on manufacturers through the back door, to use the language the Tenth Circuit used in the *Kansas v. United States* decision that we cited.

Colorado's position, again, is that even though they don't dispute that they would be preempted from imposing a price cap on Amgen's own sales of Enbrel, they can avoid preemption by imposing it on wholesaler or distributor sales. Again, as I just explained, the record is clear that it makes no difference at all. Either way the incidence of the UPL falls on the manufacturer, which here is Amgen.

So the State invokes the doctrine of patent exhaustion, and we just don't think that doctrine applies here at all. So the principle of patent exhaustion is that it is based on the common law rule against restraints on alienation. And it says that a patent owner cannot use a patent license to impose restrictions on what is done with a patented good downstream.

So once I sell it, I have exhausted my patent rights, and I have gotten the financial reward from the sale that Congress intended me to get. Here, we are not trying to exercise any control over what happens with our

drug downstream. What we are doing is objecting to the State controlling those downstream transactions in a way that prevents us from getting the reward from that initial sale that Congress intended us to get.

And so a few points about this that I think illustrate why exhaustion isn't relevant here. One is the *Bio* decision, itself. In that case, the price cap on the manufacturer or the penalty for the manufacturer was triggered by the downstream retail price. What the statute there says is the manufacturer is liable as a result of its actions. The drug is sold at retail in the District of Columbia for an excessive price.

So D.C. could have made the same argument Colorado is making here. They could have said, manufacturer, you are free to sell in that initial sale at whatever price you want, we don't care, we are not telling you as far as your wholesalers. All we are saying is that downstream, the drug had better not be sold for an excessive price.

D.C. didn't make that argument, I think because everyone understands that the downstream price and the upstream price are bound together. And if you restrict the downstream price, you are inevitably also restricting the upstream price.

THE COURT: But you would agree that the Federal Circuit in *Bio* made no ruling on that because that issue

wasn't before it.

MR. MEZZINA: Well, I actually think it was before it, Your Honor. So let me be clear.

THE COURT: The patent exhaustion issue was not before the Federal Circuit it *Bio*.

MR. MEZZINA: I am sorry, what issue, Your Honor?

THE COURT: The patent exhaustion issue was not before the Federal Circuit in *Bio*.

MR. MEZZINA: So, Your Honor that is right to the extent that D.C. did not make an argument based on patent exhaustion.

THE COURT: So you are asking me to imply something that was not expressly argued to the Federal Circuit.

MR. MEZZINA: It was not expressly argued, that is right. But the Federal Circuit did say in its decision that the D.C. statute did not directly regulate the manufacturer's own prices, it only regulated downstream prices. So I think this was implicit in the decision. The Federal Circuit recognized that with respect to the statute and says that it didn't make any difference to the law.

THE COURT: Okay.

MR. MEZZINA: I think it is also telling that the Colorado Statute shows an extensive focus on the manufacturer's list price, which is inconsistent with

Colorado's argument that the statute is really only regulating downstream prices.

So just for example, under Section 1406(1), the only factor -- the only factor that determines eligibility for an affordability review under the statute is the WAC, the manufacturer's list price, it is the only consideration.

Under Section 1406(4) the manufacturer's list price is the number one factor that is considered in an affordability review to determine whether the drug is unaffordable for Colorado consumers. And when you get to the stage of actually determining the amount of the UPL under the Board's regulations, the manufacturer's list price is also the first listed consideration at the UPL stage.

So I think all of that is inconsistent with the idea that this statute is not trying to regulate or control the manufacturer's price. It is doing that, it is just doing it according to the State, through the mechanism of controlling the price one step downstream which, again, the undisputed record is that that has the exact same effect.

So the Tenth Circuit, as I mentioned, said in the *Kansas* case that you are preempted from regulating something as a State. You can't achieve that same

preemptive result indirectly through the back door. In that case, it was these federal, you know, crop insurance contracts.

The State could not regulate the federal reinsurance, but it tried to do that effectively by regulating the private crop insurance contract that was then being reinsured. And the Tenth Circuit said, no, you can't do that. You are receiving the same preemptive result indirectly that you can achieve directly.

And I think it is the same thing here, where the record says the State is achieving the same preemptive result of capping the manufacturer's price, it is just doing it according to its interpretation indirectly by regulating the wholesaler.

And a last point on this, Your Honor, we also presented, as you know, extensive evidence that is not really disputed, that the State or the Board has targeted patent protected drugs in this process. Now, that, too, makes no sense if the statute is not interested in the manufacturer's price.

It is the manufacturer that holds the patent, that is using the list price to reap the rewards guaranteed by the patent. And so when the Board says things like, we excluded competing therapeutic competitors because they are not patent protected, because they are subject to

competition, and we subjected Enbrel to an affordability review because it is patent protected, that is further confirmation that what the state is doing is targeting the manufacturer's patent rights.

So, Your Honor, I think that is what I want to say about patent preemption. And if the Court agrees with us that this is patent preempted under *Bio*, then Court doesn't have to reach any of our claims, you have to give us full relief.

But let me turn to the due process claim. So the State's first argument here is that due process does not apply at all because this is a quasi legislative proceeding, and I think that is clearly wrong.

We cited a number of cases where courts have applied due process protections to a manufacturer in a proceeding to impose a price control on that manufacturer's product. The State has cited no case holding the opposite. And the reason for that is even though, you know, as the State says, everyone in the public is affected to some degree by what the price cap is, the manufacturer of the product is especially affected; they have a unique interest in that proceeding that triggers process protection.

In that respect, it is not that different from an IPR where obviously every member has some interest in

whether a patent is invalidated or narrowed. The Federal Circuit has said the patent owner clearly has due process rights in an IPR because they have a special interest in their patent rights. And I think it is the same thing here with a proceeding to impose price controls on the manufacturer's products.

So taking that as a given, I think what the cases say is there are two basic requirements that have to be met to satisfy due process in this context. One is there has to be meaningful standards to constrain the Board, and the second is that there have to be standards and procedures in the statute that provide for a fair and reasonable return on the manufacturer's investment.

Here, neither of those is met. Starting with meaningful standards, there is no definition in the statute or the regulations of what it means for a drug to be unaffordable for Colorado consumers. That is the most basic inquiry the statute requires. It is not defined. What there is, is a list of, I believe 12 to 15 factors, depending on how you count, all of which are sort of vaguely described and potentially cut in different directions, and the Board is instructed to consider all of these factors and then render a decision, but there is no guidance about how they weigh the factors or what might make a drug unaffordable.

THE COURT: Mr. Mezzina, let me stop you there and just go back to the basics here. What is the property right which is at stake in the due process claim that the plaintiffs are claiming?

MR. MEZZINA: Sure, Your Honor. I think there are a couple of protected interests here. So one is, as we pointed out in our brief, the Supreme Court has held that an aspect of a property right in a physical good is the ability to set the price of that good. That is the *Old Dearborn* case. The State hasn't disputed that.

So we have, as an aspect of our property right in Enbrel, that carries with it the right to set the price of Enbrel. We also have a liberty interest in being able to charge prices that we want to charge for our drug, and our liberty is restricted by the UPL. So we have, I think, both a property and a liberty interest at stake in these proceedings.

THE COURT: All right. Well, any entity can sell or attempt to market any good for any price, but it is driven, at least hopefully in our society, but what the market will bear; correct?

MR. MEZZINA: I think that is fair, Your Honor.

THE COURT: And there is no property right associated with patents that guarantees a "fair and reasonable" return. You could spend billions of dollars

developing a drug that ultimately the market doesn't demand or something else happens and the return on the investment is less than what the pharmaceutical company anticipates; correct?

MR. MEZZINA: Your Honor, I don't disagree with that. So let me be very clear, our due process argument is independent of the patent preemption argument. It is not specific to this being a patented good. These are due process principles that courts have said apply whenever a state is imposing price controls, including in the context like insurance and regulation of power rates. So this is not an argument that is specific to being a patented product.

THE COURT: Okay.

MR. MEZZINA: So just to come back to the meaningful standards point, I think a great illustration of this is the contrast between Enbrel and Trikafta. So these were two of the first five drugs considered by the Board. We pointed out in our brief, the Board determined that Enbrel is unaffordable and Trikafta is affordable, even though Enbrel is less expensive for consumers than Trikafta.

Now, I think one of the most basic ways to test whether there is sufficient standards to satisfy due process, is can regulated parties understand why I am

being treated differently from somebody else who seems to be similarly situated? And here, we have he read the 500-page report on Enbrel, the 500-page report on Trikafta, roughly, and we do not have any understanding of why the Board thinks we are unaffordable and they are affordable.

And we said this in our brief, we thought, the State is going to have to come back and explain this in some way, and they really didn't. What they said is, we have a right to apply different standards to every drug. It is not -- you know, you can't demand consistency, you can't demand an explanation of why this drug is treated one way and this other drug is treated a different way. I think that really illustrates that there are no meaningful standards guiding this affordability angle.

And then when you turn to the UPL, I think it is equally stark. So the statute directs the Board to establish a rule and methodology for determining the UPL. And it then says, here are some basic guideposts. We are not telling you the methodology, but it should consider -- here are a few things it should consider. It should include consideration of cost, and here are some things it can't do. It can't use metrics like quality-adjusted life year. But these are just some sort of basic guardrails, and the Board, you determine the methodology and issue a

ruling.

The Board issued a rule, and there is no methodology in that rule. What it does is basically just echos the statute. It says, when we are setting the UPL, we will consider the factors the statute told us we have to consider and we won't consider anything the statute told us we are not allowed to consider. But it doesn't go deeper and say how we will actually determine a UPL.

So, again, this is critical to our ability to meaningfully participate in these proceedings. If we don't understand what standards the Board is applying to how it is going to make its decisions, we don't know what argument to present to the Board, we don't know what information is going to be relevant. So even, you know, to the extent we are allowed to be heard in this process, it is not a meaningful opportunity to be heard without clear standards.

And, of course, beyond just the requirement to have standards, which is a basic element to due process, in the price control context, courts have held that there also has to be standards that guarantee a fair and reasonable return on investment for the manufacturer that is being subject to the price controls, again, not limited to the patent context.

Here, that is just clearly not satisfied. A fair

return on the manufacturer's investment is not even listed as one of the factors the Board is invited to consider in its discretion. It is certainly not a mandatory factor. That was the same thing that led the Sixth Circuit and the Ninth Circuit to invalidate the price control regimes in the cases we cited, and the state really hasn't cited anything in response to those cases, hasn't argued they were wrongly decided.

The last point on due process, I think the State, in its response to this says, well, none of this matters because, Amgen, you had an opportunity to be heard, you submitted comments, you spoke at Board meetings, and there is a real irony to this, because if you look at the record, first of all, these opportunities were extremely limited. For example, at Board meetings, we were allowed to have a representative stand up and speak for two minutes, and the two-minute limit was very strictly enforced.

But what is really telling is that we were essentially just, you know, shouting at a brick wall. We put in letter after letter and comment after comment, making some of the same points I am making here today, saying we don't understand what standards you are applying. We need more guidance. We have all of these questions that you haven't answered. And our comments

were never even acknowledged, much less responded to.

So I think for an opportunity to be heard to be meaningful, there has to be some engagement by the agency, some back and forth, some acknowledgment of concerns, some response to questions, and we had none of that.

So turning to the last two claims, on the last two claims, we actually maybe have, you know, reached some level of agreement through the briefing. So first on the federal programs claim, we argue, as Your Honor, knows, that the UPL cannot constitutionally be applied to any federal program and federal payer.

Now, the State says in response, so a month after we filed our summary judgment motion, the Board issued a non-binding policy document that says, we are not going to apply the UPL in that way. We won't apply it to any federal payer. The State argues that this satisfy the requirement for mootness based on voluntary cessation.

Now, first of all, I think everyone agrees that voluntary cessation is a heavy burden. It is the State's burden. It has to be absolutely clear that they are not going to apply a UPL in this way, and they are required to make changes that are permanent in nature.

Now, the cases they cite all involve one of two things. Either the defendant put in a declaration under penalty of perjury saying I have changed my policy, and I

say under penalty of perjury I am going to apply the new policy going forward. Or, in one case, the defendant, a district attorney, actually issued a binding legal opinion saying, I conclude that it would be illegal for me to do the thing the plaintiff doesn't want me to do.

Here, we don't have anything like that. What we have is this non-binding policy document that can be changed at any time. Nobody is required to follow it. The Board doesn't have to follow it. And the Board can change it with a stroke of a pen, just as they did in response to our summary judgement motion.

We also have a declaration from the Attorney General's Office, but that declaration adds nothing because it does not bind the Attorney General to any particular policy. What it says is the Attorney General will enforce the UPL in accordance with the Board's policies, whatever they might happen to be. So if the Board's policy were to change, presumably the Attorney General will follow the new policy.

So, you know, I really don't think we are that far apart here, but I don't think the Board has provided the kind of assurances that are present in cases finding mootness based on voluntary cessation. And so I think it would be appropriate for the Court to find and declare that the statute means what we apparently all agree it

should mean.

So turning to the final count, the commerce clause. It is the established rule that the state cannot directly regulate transactions that takes place wholly outside of the state even if the product involved in the transaction later makes its way into the state.

A number of courts have held that with respect to statutes that are basically indistinguishable from Colorado's drug pricing statutes that purported to apply to out-of-state transactions if the drug was later sold in the state downstream. The Fourth Circuit, the District of Columbia, and recently the District of Minnesota, have all held that.

The State briefly argues that the Supreme Court's decision in *Pork Producers* changed that rule, but it didn't. Every court to consider the question has said it didn't change that rule. *Pork Producers* was concerned with a situation where a regulation of in-state sales was alleged to have ripple effects outside of the state, and the court said, that is not enough. But it said in a footnote, we are expressly distinguishing our cases that do direct regulation of out-of-state sales.

Now, all of this is preparatory to saying, we may agree here, too, because the State says even though they have some disagreements with us about the law, they

ultimately say, we don't need the statute to apply to out-of-state sales, we only need it to apply to in-state sales. And that is fine, but here, this concession is not reflected in anything, it is not tied to anything in the statute, it is not in a regulation, it is not even in a non-binding policy document, it is just something the State says in its brief.

So, again, we think to have the assurance that we are entitled to, the Court should go ahead and declare that the statute means what I think the State now concedes it should mean, or at least that it is limited by the constitution, and it can't apply directly to wholly out-of-state transactions.

So, Your Honor, that concludes my argument. I am happy to answer any other questions you have.

THE COURT: All right. Thank you, Mr. Mezzina.

MR. MEZZINA: Thank you.

THE COURT: Ms. Chestnut.

MS. CHESTNUT: Good morning, Your Honor. May it please the Court.

THE COURT: Good morning.

MS. CHESTNUT: Colorado has the authority and the duty to protect its consumers from the harms caused by the lack of transparency over excessive prices in the prescription drug market. In 2021, Colorado took a bold

step to address the struggle faced by too many; the inability to afford necessary medication and it created the Prescription Drug Affordable Board.

The Board can study eligible drugs; generic and patented, to determine if their use is unaffordable for Colorado consumers. If unaffordable, the Board can bring downstream purchasers like consumers and pharmacies much needed financial relief in the form of a UPL. This work is constitutional, and summary judgment in defendants' favor is appropriate.

Amgen's claims suffer from three fatal deficiencies that permeate both the jurisdictional and merits questions in this case. First, Amgen cannot show that the Board has set or necessarily will set a UPL for Enbrel. Unless and until the Board has actually set a UPL for Enbrel, this case is not ripe.

Second, even if the Board sets a UPL, it is limited to specific downstream transactions and does not apply to the wholesaler's purchase from the manufacture. So Amgen cannot establish standing nor show that a UPL would conflict with federal law, implicate its due process rights, or unduly prohibit interstate commerce.

THE COURT: All right. So let me stop you there, because from a logical perspective, if the UPL is imposed, the plaintiffs' arguments are necessarily that there will

be upstream impact on their ability to reap the benefit of their patent rights; correct?

MS. CHESTNUT: Yes.

THE COURT: And so why is that incorrect? I mean, if you limit the downstream price, will it then not impact the upstream price necessarily? So that in the language of the Supreme Court in acknowledging standing, there could be standing for a manufacturer whose price is impacted by a downstream regulation of the price.

MS. CHESTNUT: Your Honor, we would argue that the prescription drug market is not that simple. This is a market defined by a lack of transparency, complexity, and counterintuitive behaviors. And just as an illustration, let's talk about each of those actors.

The manufacturers, like Amgen, who have a legal monopoly, say that they have to raise prices in order to compete because PBMs demand more rebates. For Amgen, this has meant that in the two-and-a-half decades it has licensed the patent for Enbrel, it has raised the WAC by over 1,500 percent, dramatically outstripping inflation.

Wholesalers routinely sell the drug for less than they bought it for, which is why there is an established norm of discounts and charge backs between manufacturers and wholesalers. It is also why they offer other services to manufacturers in exchange for fees, because

compensation based on the distribution of the drug alone isn't sufficient to sustain its business model. And these contracts are also typically long term, pre-negotiated bulk deals covering nationwide distribution for multiple drugs.

PBMs, for their part, are supposed to negotiate discounts for consumers, absorb confidential rebates based on higher prices charged by the manufacturer, and driving the consumers to the drugs that give the PBMs the best charge back. In all of this, the consumers are the ones who are left the most in the dark.

Opacity is a feature of the prescription drug supply chain, not a bug. There is normally transparency among these different supply chain actors, and they routinely point the finger at the other one saying that they are responsible for raising the cost of the drugs.

So, Your Honor, we would agree that it is possible that there would be an incidental impact of the UPL that could be felt by the manufacturer, but it is also possible that there would not be. The impact of a downstream regulation on some purchases of one drug in one state is unknown.

And just like any other regulation that could increase the cost of doing business, it will be for the wholesaler and the manufacturer to make a business

decision if and when a UPL is set on whether to internalize those regulatory costs in their contracts.

Colorado is the first state in the nation to potentially set a UPL. So nothing about this is predictable, and we shouldn't decide the constitutionality of the entire statute based on speculation.

THE COURT: All right. So what, in the State's perspective, would plaintiffs have to show in order to establish standing; that there would be some more than speculative injury in fact?

MS. CHESTNUT: More. I think, Your Honor --

THE COURT: When you say "more," what do you mean? How much more?

MS. CHESTNUT: So if a UPL is set, and at that point -- and a UPL is effective six months after the adoption of the rule. So supply chain actors have six months to figure out how it will implement an actual UPL. It is not even a guarantee that a UPL would actually change the prices currently being bought and sold for that drug in Colorado. And so unless and until we actually know that a specific UPL is going to change business decisions, we don't know how the supply chain actors are going to implement that UPL.

THE COURT: How would a UPL not affect that if the whole focus of the statute is to regulate the price or, as

you said in your introduction, make drugs more affordable to the consumers in Colorado?

MS. CHESTNUT: Well, Your Honor, I think we need to see the Board's process play out. We need to see what data becomes available during the UPL rulemaking to see when and if the Board actually sets a UPL. But because the relationship and the supply chain are so complex, these are usually both deals -- you know, pharmacies are purchasing a multitude of drugs from wholesalers at a given time. Wholesalers are purchasing a multitude of drugs from the manufacturer at a given time. It is not beyond the realm of possibility that there are give and takes in those contractual relationships where maybe these actors say, we will take a loss on this drug because we know we are going to be able to make it up on this other drug.

We just don't know without specific information how the supply chain actors are going to implement an UPL. So until Amgen, for example, could bring, for example, declarations from its actual distributors saying how they would implement a UPL, saying what the actual cost it would be to the manufacturer, what the manufacturer will be getting less from, until the manufacturer can do more to show that there will be an actual impact to it and it wouldn't just be absorbed, there isn't standing.

THE COURT: But is actual impact what is necessary for standing?

MS. CHESTNUT: We would argue, yes, that a concrete injury is necessary.

THE COURT: A concrete injury or a particular injury in fact doesn't necessarily mean the injury is, in fact, necessary. Is that what you are saying that standing is; that they would have to go through this entire process, have years pass by, make sure that the market actually bears out an injury to the price of this drug, that I would have to somehow take into account these bulk sales in order to determine whether or not they merely had standing to get into court? So that is different, potentially, although I am not sure it is in this case, than merit, but standing is just the doorway into the courthouse.

MS. CHESTNUT: Correct, Your Honor. And, you know, at the outset, we would say that pre-enforcement standing isn't applicable here because Amgen can't actually show that the statute would either be directly applied to it or enforced against it.

But, in any case, they have to show that the injury is sufficiently imminent; that it is actually going to happen. Yet, we agree, Your Honor it doesn't necessarily mean they have to wait for a concrete injury in every

case, but they have to show that it is actually going to happen. This a novel regulation, so we just don't know that that is going to be the case.

THE COURT: Okay.

MS. CHESTNUT: Whether Amgen can show that it has standing comes down to which transactions a UPL applies to and whether any effects during the UPL will predictably injure Amgen as the manufacturer.

So regarding where the UPL applies, let's imagine that the Board has set a UPL price for a drug. The UPL applies to consumer's purchase from the pharmacy. If the consumer is insured, it applies to the state-regulated insurance company for reimbursement to the pharmacy, and it applies to the pharmacy's purchase from the wholesaler.

The pharmacy, as the entity dispensing the drug in Colorado, is the one responsible for knowing when the UPL applies, and that is it. That is what is supported by the statute, it is supported by the legislative history. The UPL does not apply to the wholesaler's purchase from the manufacturer.

The statute's aim has always been about bringing downstream relief for consumers, providers, pharmacies, and insurance companies struggling in Colorado with the excessive costs and unequal bargaining power in the prescription drug market. It has never been about telling

the manufacturer what to charge.

The statute regulates downstream actors, not Amgen. So this undermines Amgen's standing and the merits of each of its claims. Amgen would have this Court prematurely decide the constitutionality of an entire statute that is yet to be fully applied, eviscerating Colorado's power to protect its consumers.

Amgen wishes to control downstream market conditions so that it can be free from indirect regulations that might make its business less profitable. This is not a result compelled by the Constitution nor an appropriate use of this Court's jurisdiction.

Your Honor, unless there are other questions regarding the jurisdictional matters in this case, I intend to move on to the merit issues.

THE COURT: Go ahead.

MS. CHESTNUT: Thank you. First, the Board's work is not preemptive. Patent law is designed to give a limited monopoly. This monopoly gives Amgen the right to determine to whom, where, and for how much it will sell Enbrel for. It doesn't guarantee a particular price, nor does it give Amgen the right to be free from regulation.

THE COURT: Do you agree that the Federal Circuit, to the extent that the Court makes a determination on the patent preemption issue, would be the controlling circuit

court?

MS. CHESTNUT: Yes.

THE COURT: So why isn't *Bio* controlling in this case?

MS. CHESTNUT: *Bio* is distinguishable for two main reasons. So first and most importantly, the D.C. law there directly prohibited the manufacturer from charging an excessive price. The manufacturer was the one specifically on the hook under the D.C. law.

The Federal Circuit found that this direct prohibition on the manufacturer significantly and directly interfered with their rights to receive above-market profits during the patent time. But that is not what a UPL would do.

A UPL is a downstream regulation that doesn't apply to the wholesale's purchase from the manufacturers, so *Bio* is inapposite on this point. And second, the *Bio* court discussed how critical it was for its analysis that the D.C. law focused only on patented products, but the Board's work applies to patented and generic products alike.

But, in any case, *Bio* is also not unlimited in application, because 10 years later, in *Impression Products*, the U.S. Supreme Court held that patent rights do not guarantee a particular price. Rather, once a

patentee sells its product for a price, it deems satisfactory it has received its reward and exhausted its rights.

So reading these two cases, the Federal Circuit and the Supreme Court left the door open for a law just like Colorado's; one that could incidentally impact a patentee's profits that was enacted under state's police power regulating downstream purchases after the rights have been exhausted.

Colorado's law isn't aimed at upending patent rights, but at protecting consumers by rebalances bargaining power. So this is exactly the type of law that doesn't significantly or directly interfere with the obstacles of patent law and the ability to make a profit.

Amgen still has the choice of when to sell its drug to a wholesaler, how much, and it can decide whether or not it's received a satisfactory price even if a UPL is set. Amgen and the wholesalers are in control of their business decisions, they still get their carrots.

States pass registrations that impact the cost of doing business all of the time. They pass safety regulations and registration and licensing schemes. They require fees for companies doing business, and they tax. If every state regulation that incidentally impacted profit margins conflicted with federal patent law, state

police powers would be eviscerated, so Amgen cannot prevail on this claim.

THE COURT: So would *Bio* apply if it only applied to downstream purchases of patented pharmaceuticals? So let's just -- I mean, they are here on a patent issue, a patent preemption issue. I am assuming that Mr. Mezzina would concede that if the patent expires or is invalidated somehow, that argument falls away, although he would argue that the other challenges to the statute might continue on, although potentially just the due process given his arguments about the federal preemption and other issues.

So would you agree then that *Bio* would apply if the Colorado Statute was limited to patent products; patented drugs are the only ones that would be able to be to get a UPL?

MS. CHESTNUT: We would still argue, Your Honor, that *Bio* a distinguishable on the other feature, which is that the UPL would be a downstream regulation. So whether that is being applied to patented products or generics or patented products that the patent term has expired, at any rate, the UPL is still a downstream transaction. And so because *Bio* is focused on a direct regulation on the manufacturer, what the manufacturer could charge, they are regulating in different spheres. And the UPL, in any case, wouldn't interfere with the patentee's ability to

set its price.

THE COURT: Okay.

MS. CHESTNUT: Moving on to due process, Amgen also cannot show that the Board's work violates due process. To bring a procedural due process claim, Amgen must point to a legally protected property right and a deprivation of that right by the Board without notice and opportunity to be heard. But at every step of this analysis, Amgen comes up short.

Neither the affordable review nor UPL impacts Amgen's rights. My opposing counsel spoke about the focus of the Board on WAC, wholesale acquisition costs. But putting this in context, WAC is one of 15 factors that the Board evaluates when looking at the affordability review. It is one of 10 numbers that the Board evaluates when setting an upper payment limit.

It is simply not the case that the Board's statute is focused on the manufacturer. The Board's statute is focused on downstream actors; consumers, providers, pharmacies, insurance companies. We see this even from the statute.

The UPL methodology that the Board is directed to promulgate has to take into consideration the cost of dispensing, administering, and distributing the drug. Dispensing the drugs, focusing on pharmacies.

Administering the drug, focusing on providers. And dispensing the drug, focused on wholesalers. It simply is not the case that this work is focused on the manufacturer.

The affordable review is the Board's study of affordability issues for Coloradoans accessing a particular drug, it is not a judgment on a manufacturer's price. And nothing in the real world changes if the Board deems a drug unaffordable, nor does the UPL, which does not apply to Amgen, adjudicate Amgen's rights. Rather, the Board engages in a prospective generally applicable setting of a payment amount that applies to consumers, pharmacies, providers, and insurance companies alike.

Setting a UPL is quasi legislative. And this quasi legislative process through rulemaking also gives a public process for stakeholders, including Amgen, to participate in. Amgen can come in that UPL proceeding and tell the Board what it thinks the UPL should be. A UPL rule is also a final agency action. It is reviewable by the courts and the legislature. So the Board's authority just is not as limitless as Amgen paints it out to be.

Amgen argues that an opportunity to be heard isn't meaningful if there aren't enough standards, but in doing so, misses the forest through the trees. Amgen is only entitled to the opportunity to be heard if the Board is

depriving it of a property right in an adjudicatory proceeding, and that is not what is happening here.

And, regardless, the Board's work does have standards. The legislature doesn't have to give an exacting formula to an agency every time it delegates discretion and decisionmaking. It if wanted to be this prescriptive, it could have come up with the formulas itself and obviated the need for a board of experts.

Instead, like numerous boards and commissions before it, Colorado chose to create the Board, giving it abundant criteria to consider in evaluating the nuanced and complex context for the different drugs it reviews. This work comports with due process.

Moving on to Amgen's other preemption argument, the claim that future UPLs set by the Board are preempted from applying to federal healthcare programs is moot. Since January of 2023, so for nearly two years, by rule and policy, the Board has stated that a UPL does not apply in these circumstances.

The Board's rule explicitly states that a UPL applies to purchases and reimbursements by carriers, which is defined as insurance companies regulated by the state; state entities; and then claims regulated by ERISA that voluntarily opt in to a UPL. The Board's policy also states that the UPL does not apply to purchases or

reimbursements made by the federal government or other sovereign actors such as Native tribes.

This is not the Board trying to play games in litigation to avoid review. This is the Board, and then the AG on the enforcement side, narrowly construing their authority predating this litigation. There is no live controversy, so Amgen's claim regarding preemption is moot.

Finally, concerning the dormant commerce clause.

THE COURT: Can I ask you a question about the rule? So, Ms. Chestnut, your argument is that because the federal entities, such as the Federal Employee Health Benefit Plan and other federal programs are not included within the rule as defined parties, then that should be interpreted as they fall outside of the statute under the UPL. Is that your argument with respect to the rule?

MS. CHESTNUT: Yes, Your Honor. We would argue that the statute didn't enumerate every person or every transaction that the UPL applied to. And so the Board has the most faithful interpretation of the statute given the legislative history, given the structure of the statute. And so by promulgating the rule that explicitly defines the entities that the UPL applies to, because these federal healthcare programs such as Medicare, such as the Federal Employee Health Benefits Plan, are not included in

this definition, they are excluded.

THE COURT: Okay.

MS. CHESTNUT: Finally, the Board's UPL authority also does not run afoul of the dormant commerce clause for three reasons. First and foremost, because the anti-discrimination principle at the core of the commerce clause is not implicated in the Board's work, the UPL established by the Board applies equally to in-state and out-of-state actors.

Second, the dormant commerce clause's restriction on the state controlling a price on an out-of-state transaction is not at issue here because that limitation only applies when price of the in-state product is tied to the price charged out of state. The Supreme Court just clarified this limiting principle just last year in *National Pork Producers Council v. Ross*.

And, third, Amgen cannot prevail under the *Pike* balancing test because it cannot show that the burdens of a UPL on interstate commerce are excessive when compared to the benefits to Coloradoans, and the UPL has no discriminatory effect.

Amgen concedes that Colorado has the authority to regulate transactions where at least one person is in Colorado. It takes issue only with the transactions that are occurring entirely out of the state. But just as *Pork*

Producers choosing to do business in California could be required to change their out-of-state business operations to comply with the California law, pharmacies choosing to dispense drugs subject to a UPL in Colorado can be required to comply with the UPL regardless of where they are located.

To conclude, without an actual UPL, this case is not ripe and Amgen cannot show that it has standing. But even on the merits, defendants prevail on each of Amgen's claims because the UPL is a downstream regulation that does not conflict with federal law, implicate Amgen's due process rights, or burden interstate commerce.

Colorado has the power and duty to protect its consumers from the harms caused by the prescription drug market and it has constitutionally done so. Defendants request summary judgment in their favor.

Your Honor, I would like to reserve the opportunity to come back up. If there are no further questions.

THE COURT: Thank you. Mr. Mezzina.

MR. MEZZINA: Thank you, Your Honor. I want to start with standing. And so the State articulated the standard as we have to show that the Board has set or necessarily will set a UPL, and respectfully, I just don't think that is the right standard. *Susan B. Anthony List*, the standard is a substantial risk or, as the Federal

Circuit said, a realistic danger. We cite a number of cases --

THE COURT: What about the causation prong? What about the fact that you also have to establish a predictable chain of events leading from the government action to the asserted injury; in other words, that the government action has caused or will likely cause injury in fact to the plaintiffs.

MR. MEZZINA: Sure, Your Honor. So the "will likely cause" prong of that, I don't know how we could have failed to satisfy that. We put in a declaration that is explicit. It explains in detail exactly how this market works, exactly how the contracts work, and it says there is no realistic chance that wholesalers will absorb the discount required by the UPL. That is just not how this industry works. It is not how our contracts work. It says it is a certainty that that cost will be passed onto Amgen.

There is no rebuttal to that. This is summary judgment. The State cannot rebut a declaration with attorney argument. And even the attorney argument doesn't really respond to Mr. Costello's explanation.

So my friend says that the pharmaceutical market is complicated. And I agree there are aspects of the market that are complicated. But the part we are focused on here

is not complicated, it is very simple. The manufacturer sells a drug to a wholesaler at the WAC, the list price. The wholesaler turns around and sells that same drug to a downstream purchaser, either at the list price or at a discount. And if it is at discount, the manufacturer has to make the wholesaler whole for that discount.

That is what the declaration says, and the State does not attempt to refute that. They don't say that that is wrong, that it is an inaccurate description of how this would actually work. And, in fact, they are the ones who quoted the statement from the legislative sponsor that described the market working in exactly this way.

So Representative Kennedy says exactly what I just said. He says, we know how these relationships between manufacturers and wholesalers work. We expect that they will continue to work the same way. And if the wholesaler has to sell at the UPL, it will be made whole on the back end by the manufacturer. The legislature knew that. We created a record that supports that, and there is no rebuttal to that record.

So I don't think there is any speculation necessary here. I think we have done everything we needed to do to make a record on this, and I really don't know how we could have done any more.

My friend made the point that the statute would not

be directly enforced against us. We cited a number of cases where the parties would deem to have standing even though the statute, a regulation they were challenging, would be enforced against a third party. One example of that is the D.C. Circuit case involving the Biofuel producers, they were challenging, I believe an EPA regulation that limited the downstream use of Biofuels, and the D.C. Circuit thought it was obvious that they had standing to challenge that regulation even though they were not the directly regulated parties, said this regulation on downstream use is restricting your market, and so it is injuring you. And the D.C. Circuit -- and this was Justice Kavanaugh writing for, I think, a unanimous court, gave a number of examples.

He said, for example, if the state were to make it harder for concession stands to sell hot dogs, we would all understand that the hot dog manufacturer was injured by that because it is affecting their market. And this is no different here, even -- and, again, I don't want to lose sight of the fact that this limitation is nowhere in the statute.

But even taking the limitation as granted, I just think it is very clearly that restricting what can happen to our drug downstream, and one step downstream, one step removed, is going to affect us and injure us, and we made

clear exactly how that would happen.

So one more point on the standing issue, is even if you set all of that aside, and you say maybe there is some way that you could work this out with your wholesalers so that you don't have to make them whole, it is undisputed that that is how the industry works, that, itself, would impose costs.

So one of the things the Federal Circuit says in *Bio* is even if no manufacturer is ever subject to a proceeding under the D.C. statute, they will still be negatively affected because they are going to have to, not only set their own prices, consider this statute as a background, it is going to influence their own pricing decisions, and so even without a proceeding, that injury would be enough for standing. Here, as I said, we are miles past that because we are actually currently subject to a proceeding, which no plaintiff in the *Bio* case even could say that.

So turning to preemption, so you know, I think we have a certain amount of agreement about what exhaustion means. My friend said Amgen has the right to determine for how much it will sell the drug. For exhaustion to come into play, we have to have that unburdened initial sale opportunity. This is what the Supreme Court says in *Impression Products*.

The reason our patent right is exhausted is because we are able to get our reward from that initial sale. And once that happens, we have gotten what Congress wanted us to get out of the patent, right, we've gotten that financial reward. If the State regulates downstream in a way that inevitably affects our upstream sale and prevents us from getting that reward, then the one can't be exhausted.

THE COURT: So wouldn't that be true on any state regulation? So, for instance, if a state regulated how much safety needed to be in a car --

MR. MEZZINA: No, Your Honor. I am sorry.

THE COURT: -- wouldn't that, under your argument, wouldn't that always give the manufacturer standing, because your argument is that it going to flow upward?

MR. MEZZINA: It might, in fact, give us standing if we could show injury causation. I am not sure about that because standing is, as Your Honor noted, is just sort of a threshold requirement to get into court. But I don't think it would be patent preempted.

And the Federal Circuit drew a distinction between sort of general actual regulations that incidentally, you know, raise the cost of doing business, something like a licensing requirement, a general safety regulation, even general tort law affects the cost to do business.

The Federal Circuit said those kind of things are not preempted. What is preempted is a specific regulation of price. And in an attempt to say, the reward that Congress gave the manufacturer in order to encourage the progress of science and useful art, the Congress determined very carefully pharmaceutical manufacturers should have this financial reward during the period of the patent. And the Federal Circuit said, a price control directly undermines that incentive.

So that is very different from something that is just an incidental regulation. And, you know, my friend described this as incidental. Again, I just think that is completely inconsistent with the record here. We have showed that there is a one-to-one relationship; that applying a UPL to our wholesale and distributor partners directly translates one to one into a cost for Amgen in our upstream sale.

There is just no evidence in the record to contradict that. The legislature understood that. So this is very far from just an incidental impact on our price.

Again, confirming that is WAC, my friend talked a little bit about how WAC plays a role in the statute, but she doesn't dispute that WAC is literally the only facet the statute requires the Board to consider to determine

whether a drug is eligible for an affordability review.

So at the outset of this process, the Board is only looking at the manufacturer's list price. I also think it is worth noting the implications of this argument, if it is true that we have no ability to object to any downstream regulation, they could set the downstream price at a dollar, they could require wholesalers to give the product away for free, and on their theory, we couldn't complain about that because it is just an incidental effect on our price, even though obviously if the wholesaler is limited to selling the product for a dollar, we are not going to be able to get our financial reward from selling to the wholesaler.

So I really think this would just be a way of nullifying the Federal Circuit's *Bio* decision. And let me explain that. We have two amicus briefs representing a broad swath of the pharmaceutical industry, and they explain the way this works for Amgen is the way it works for the whole industry. And if you could evade *Bio* in this way by saying we are just going to cap the price the wholesaler can charge, *Bio* would be a dead letter. You could achieve the exact same price control impact on the manufacturer just by regulating this way.

So let me turn to due process. I think my friend's first argument was this has no impact on our rights. I

think that's addressed by everything I have said about standing and preemption. Again, we have a factual record at summary judgment that this directly and clearly impacts our rights, and that is unrebutted.

My friend said there are 15 factors the Board considers, so I guess I was a little low with my estimate of 12 to 15. There are, in fact, 15 factors. And there is, again, no guidance on how to weigh those factors. We still didn't get any explanation of the disparate treatment of Enbrel and Trikafta, which I think just drives home the point that the standards are not clear enough for a regulated party to understand what the Board is doing.

There is still no case that has been cited holding that a price control proceeding is quasi legislative. Every case that we have been able to find, and we have cited a number of them, hold that manufacturers have due process rights in these kinds of proceedings.

And, finally, my friend said the legislature doesn't have to provide an exacting formula. I don't disagree with that. We are not asking for an exacting formula, we are asking for some comprehensible meaningful standard so that we know what the Board is doing and we know what kind of arguments and what kind of factual information we need to provide to influence the Board's

decision.

If we don't understand that, then our ability to submit comments and our ability to speak for two minutes at a meeting isn't meaningful because we don't know what standards we need to address. And, of course, in the one instance where the legislature did instruct the Board to come up with something resembling a formula, where it told the Board, you need to come up with a methodology for setting a UPL, the Board didn't do that, it just echoed the criteria in the statute and it didn't supply methodology.

On the federal programs preemption point, so the State argues that it is not -- it doesn't have to rely entirely on the non-binding policy document, it can rely on the rule. I know this is an argument the State didn't make until its reply brief. In its initial response brief it only relied on the policy document. I think that, by itself, is pretty strong evidence that the rule is not sufficiently clear on this point.

The rule includes a number of ambiguous terms, including the UPL applies to a pharmacy, a provider, a consumer, any of which could potentially encompass a federal program. So, for example, a pharmacy, the VA runs hospitals, it runs pharmacies. Are those providers? Are those regulated pharmacies? It is not clear from the

regulation.

My friend also cited the definition of carriers, but I think that argument is circular here. Carriers is defined as essentially -- and, I am sorry, I am quoting from memory, but it is health benefit plans that are subject to the laws and rules of Colorado.

Of course, our contention here is that the federal programs are not subject to Colorado law, but that is not clear -- it is not clear from the definition that Colorado agrees with that. That is the issue in dispute.

And just, you know, a final point on this. To the extent that the Court has to construe a rule or construe the statute in order to overcome our claims, that is not mootness. Mootness is a threshold jurisdictional issue. If the case were moot, the Court would have no authority to even construe the statute or the regulation.

So if what satisfies our claim is that the Court gives the regulation a stated construction, that necessarily means our claim is not moot, it means the Court should issue a judgment adopting that stated construction.

And courts do that all of the time in constitutional challenges, where the State says this statute is not unconstitutional because it should be construed in such and such way to avoid constitutional

battle. If the Court agrees with the State and accepts its argument, it doesn't dismiss the claim as moot, it says, I am adopting the State's construction and that addresses the constitutional concern. And so the Court could do the same thing here.

What I just said also applies to the dormant commerce clause. Although it is a little concerning that although the State said in its brief that it does not think that the statute applies to out-of-state transactions, I did not hear that concession today. Instead, I just heard an argument that it would be okay if the statute did apply to out-of-state transactions.

So I am not completely sure what the State's position on that is. To the extent the State is prepared to concede that the statute should not be read to apply to out-of-state transactions, which I think was its position in its brief, we can agree on that, and the Court can declare that and adopt that as a stated construction.

But to the extent the State is disputing that, I really disagree with their reading of *Pork Producers*, as does every court that has looked at this issue. *Pork Producers* was very clearly about a law that said pork sold in California has to meet certain standards. And the plaintiffs are saying, as a practical matter that is going to impact what we do in other states. And the Court said,

that is true of lots and lots of state laws. That practical impact out of state is not a sufficient basis for invalidating a law under the dormant commerce law.

But it said in footnote 1, it distinguished -- the court suppressed it in *Edgar.* The court says, says: But a state cannot reach out and directly regulate that out-of-state transaction. Now, if that is what Colorado is trying to do, that is inconsistent with *Edgar*, it is inconsistent with *Healy*, and it is inconsistent with *Pork Producers*.

So unless Your Honor has more questions, I think I will just close with a point I tried to make earlier. I really do think this case is all about *Bio* and how easy it is going to be for states to effectively nullify *Bio* through backdoor regulation.

We have made a clear record, both with our submissions and our briefing, that the State's theory would permit exactly that. It would allow every state to impose the exact price controls that *Bio* said are preempted, just doing it in a very slightly roundabout way. And I think that would be inconsistent with the Constitution and inconsistent with the respect that is due to the Federal Circuit's decision.

Thank you, Your Honor.

THE COURT: Thank you.

Ms. Chestnut.

MS. CHESTNUT: Thank you, Your Honor. I just would like to respond to a few points.

THE COURT: All right.

MS. CHESTNUT: The first is that, you know, my friend discusses at length that this is necessarily going to impact the wholesalers, but I just again want to bring us back to, it was a business decision between the wholesalers and the manufacturers to structure their contracts in a way that causes, you know, an automatic discount or anything being passed on to the manufacturer.

That is a business decision that can also be undecided. They can renegotiate their contracts. They can structure them however they please if Amgen is unsatisfied with the price that it is selling the product for when it sells to the wholesaler.

THE COURT: That doesn't really change the Costello declaration, does it? I mean, the fact that they can restructure it so that they don't have an injury, how does that address the Costello declaration that says, at summary judgment, when you come forward with evidence that there is an injury to them?

MS. CHESTNUT: Your Honor, we would make two points. So the first is that Amgen is still the one choosing to sell to the wholesaler, and it decides whether

or not the price is satisfactory. So if it also -- you know, if the wholesaler is also demanding some sort of a charge back or a discount on the back end, that is not changing that the rights of Amgen exhaust as soon as it makes the sale to the wholesaler.

So beyond that, we have no --

THE COURT: But they can't make the sale to the wholesaler at the price that they want to because of this downstream regulation. So how is that not an injury in fact that is traceable upstream?

MS. CHESTNUT: Well, Your Honor, again, that, we would say, is undermined for a couple of reasons. So the first is that this -- you know, we would still argue it is not predictable. This is a really novel state regulation, and we don't actually know that that is actually how these entities are going to respond.

But even if they did, we would say that that is not enough to create standing. That is a contractual decision, a business decision between the two of them that doesn't change the nature of the regulation at issue. And so the UPL is still not directly regulating the manufacturer's price, that is the wholesaler and the manufacturer deciding something on the back end.

THE COURT: Okay.

MS. CHESTNUT: And, Your Honor, I would just like

to come back again to the point of the *Impression Products* case. The Supreme Court there very clearly stated that patent law does not guarantee a particular price, just a reward. And Amgen decides when it gets that reward and whether or not it is satisfactory. When it sells to the wholesaler, it receives that reward, even if there is some discount or charge back that they privately negotiated. It doesn't change the exhaustion principle at issue here.

Turning to due process, unless there are other questions on the patent preemption piece.

THE COURT: Go ahead.

MS. CHESTNUT: Turning to due process, I want to speak for just a moment about how judicial review really keeps the extremes presented by Amgen in check here. So the statute directs the Board to consider certain factors, both in the affordability review and the UPL. And we agree that the statute doesn't clearly state how, necessarily, the Board should consider those factors or how to weigh them. It gives the Board flexibility to do so.

But judicial review is enough to cabin the Board's discretion. The Colorado APA provides that a court can set aside an agency rule if the action is arbitrary and capricious; contrary to a constitutional right, power, privilege, or immunity; in excess of statutory

jurisdiction, authority, purposes, or limitation; and abuse of discretion or clearly unwanted warranted exercise of discretion based on findings of fact that are clearly erroneous on the whole record or unsupported by substantial evidence when the record is considered as a whole.

So in a judicial review action, the Court asks the familiar question: Was this a reasonable decision? Did the agency review the information it was directed to under the statute? State boards and commissions makes these types of discretionary determinations all the time and courts review them all of the time.

So Amgen's extreme, you know, hypothetical about a $1 UPL really just isn't realistic when considering the whole public process that any sort of UPL would go though, as well as the ample procedural protections on the back end.

Finally, Your Honor, I want to turn to the dormant commerce clause.

THE COURT: Okay.

MS. CHESTNUT: I want to clarify that it is the defendants' position that a UPL would apply to an out-of-state transaction if that transaction is a pharmacy's purchase for a drug that is to be dispensed in Colorado. So if we, for example, have a mail order

pharmacy and, you know, purchasing from an out-of-state distributor and both parties are out of state, as long as that drug is destined for Colorado, we believe that the UPL does apply to the pharmacy's purchase from the wholesaler for that product.

And we believe that this is in line with the analysis that the Supreme Court applied in *Pork Producers* that really is indistinguishable from this case. If we have a pharmacy, whether in state or out of state, because there is no discrimination here, but if we have a pharmacy that is choosing to do business in Colorado by dispensing those drugs in Colorado, then they can be subject to the laws of Colorado even if the effects of that law would be on interstate commerce in some way.

Amgen still has not demonstrated that the burden on interstate commerce is undue or that it would outweigh the benefits to Coloradoans, and so in any case, this law passes and survives the dormant commerce clause.

Finally, Your Honor, I want to read the footnote from the *Bio* case where the Federal Circuit denied rehearing en banc, and the author of the Federal Circuit's decision authored a concurring opinion, and in this footnote to his concurring opinion he states: This does not mean that any state regulation that affects the patentee's profits so undermines the goals of the patent

system as to be preempted. It is well established that states can generally regulate patented products as part of their general exercise of police powers without preemption even if this regulation incidentally affects the profits a patentee gains from its patent. Because the states have broad leeway to regulate patented products does not mean that they have the unlimited ability to do so in situations in which the regulations significantly or directly impede Congress' purpose in providing the federal patent rights.

Your Honor, that is not what is happening here. Without a UPL, this case is not ripe, but in any case, defendants prevail on the merits and request summary judgment in their favor.

And if there are no further questions.

THE COURT: No further questions. Thank you.

All right. Pending before the Court are the parties' cross motions for summary judgment, that is Docket Entry No. 24 and I believe Docket Entry No. 29. The Court has taken these arguments and the briefing under advisement and we will issue a written order as soon as possible.

Anything further on behalf of plaintiffs?

MR. MEZZINA: No, Your Honor.

THE COURT: Anything further on behalf of

defendants?

MS. CHESTNUT: No, Your Honor.

THE COURT: All right. Thank you very much. We will be in recess.

(Proceedings conclude at 11:26 a.m.)

R E P O R T E R ' S C E R T I F I C A T E

I, Darlene M. Martinez, Official Certified Shorthand Reporter for the United States District Court, District of Colorado, do hereby certify that the foregoing is a true and accurate transcript of the proceedings had as taken stenographically by me at the time and place aforementioned.

Dated this 28th day of October, 2024.

_____

s/Darlene M. Martinez

RMR, CRR