**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF KANSAS**

ABBVIE, INC., et al.
Plaintiffs,

v.

KRIS KOBACH, in his official capacity as the Attorney General of the State of Kansas,
Defendant.

Case No. 6:24-cv-01111-KHV-GEB
(Lead Case)

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ASTRAZENECA PHARMACEUTICALS LP,
Plaintiff,

v.

KRIS KOBACH, in his official capacity as the Attorney General of the State of Kansas,
Defendant.

Case No. 6:24-cv-01112-KHV-GEB
(consolidated with 24-cv-01111-KHV-GEB)

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PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,
Plaintiff,

v.

KRIS KOBACH, in his official capacity as the Attorney General of the State of Kansas,
Defendant.

Case No. 6:24-cv-01132-KHV-GEB
(consolidated with 24-cv-01111-KHV-GEB)

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NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff,

v.

KRIS KOBACH, in his official capacity as the Attorney General of the State of Kansas,
Defendant.

Case No. 5:24-cv-04068-KHV-GEB
(consolidated with 24-cv-01111-KHV-GEB)

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**Motion for Judgment on the Pleadings or, in the alternative, for Summary Judgment**

Attorney General Kris Kobach moves for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c), or in the alternative, judgment as a matter of law pursuant to Fed. R. Civ. P. 56.

## I. Nature of the Case

This is a § 1983 action for declaratory and injunctive relief. Plaintiffs, pharmaceutical manufacturers, assert 2024 Senate Bill 28 violates their constitutional rights. In the four consolidated cases, Plaintiffs assert the following claims:

I. Violation of Takings Clause, U.S. Const. amend. V, cl. 4
II. Preemption under the Supremacy Clause:
  A. Preemption under § 340B; and
  B. Preemptions under federal patent law;
III. Violation of the Due Process Clause of the Fourteenth Amendment of the U.S. Constitution, unconstitutionally vague/void for vagueness;
IV. Violation of the Due Process Clause of the Kansas Constitution, void for vagueness;
V. Violation of the One Subject Rule under the Kansas Constitution.

Other than the 340B preemption claim, Plaintiffs' claims are not identical. For the convenience of the court, this identical motion and brief is filed in each of the four cases and addresses all claims. The following table is provided to clarify which plaintiff asserts which claims:

| **Abbvie 24cv1111** | **AstraZeneca 24 cv1112** | **Novartis 24cv4068`** | **PhRMA 24cv1132** |
|---|---|---|---|
| Count I<br>Takings Claim | Count IV<br>Takings Claim | | |
| Count II<br>340B Preemption | Count I<br>340B Preemption | Count I<br>340B Preemption | Count I<br>340B Preemption |
| | Count II<br>Patent Law Preemption | Count II<br>Patent Law Preemption | |
| | Count III<br>Contracts Clause | | |
| Count III<br>Unconstitutionally vague (federal) | | | Count III<br>Unconstitutionally vague (federal) |
| Count IV<br>Unconstitutionally vague (state) | | | |
| Count V<br>One Subject Rule | Count V<br>One Subject Rule | | |

S.B.t 28 has a single subject—it appropriates money. S.B. 28 does not regulate the conduct of pharmaceutical manufacturers. S.B. 28 § 32(g) and § 33 direct the Attorney General to expend

appropriated money, *inter alia*, to enforce the Kansas Consumer Protection Act (KCPA) Plaintiffs do not allege that Plaintiffs are presently violating the KCPA nor do they allege that they intend to violate the KCPA in the future. This Court lacks subject matter jurisdiction because Plaintiffs lack standing and there is no case or controversy. Without regard to the lack of standing or a case or controversy, Defendant is entitled to judgment on the pleadings or judgment as a matter of law because the Plaintiffs do not state claim upon which relief may be granted.

Before addressing the various reasons Defendant is entitled to judgment, it must be acknowledged that the slate for plaintiffs' claims is not blank. Substantially the same claims have been raised elsewhere involving other states and their officials. *See, e.g.,*

- *Pharmaceutical Research and Manufacturers of America (PhRMA) v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *2 (W.D. La. Sept. 30, 2024) (granting summary judgment to Louisiana's Attorney General in three cases by AstraZeneca, AbbVie, and *PhRMA* and rejecting claim that Louisiana's Act 358 was unconstitutional based upon field preemption theory, conflict preemption theory, vagueness theory, Contracts Clause theory, and Takings Clause theory).

- *PhRMA v. McClain*, 645 F. Supp. 3d 890 (E.D. Ark. Sept. 12, 2022), *aff'd*, 95 F.4th 1136 (8th Cir. Mar. 12, 2024) (granting summary judgment to Arkansas Insurance Department Commissioner on claim Arkansas statute was unconstitutional based on field preemption theory, impossibility preemption theory, and obstacle preemption theory),

- *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. Mar. 12, 2024) (affirming grant of summary judgment);

- *Novartis Pharms. Corp. v. Fitch*, No. 1:24-CV-164-HSO-BWR, __F.Supp.3d__, 2024 WL 3276407, at *7 (S.D. Miss. July 1, 2024) (appeal to Fifth Circuit Court of Appeals filed, No. 24-60342 Jul. 9. 2024) (denying preliminary injunction on field and conflict preemption theories); and

- *AbbVie Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965, at *16 (S.D. Miss. July 22, 2024) (appeal to Fifth Circuit Court of Appeals filed, No. 24-60375 Jul. 24. 2024) (same, denying preliminary injunction based on field and conflict preemption theories, , and takings theory).

Other states have enacted similar legislation, and similar cases are pending in other districts:

- ***Louisiana*:** *PhRMA v. Landry*, 23-cv-997;

- ***Maryland*:** *Novartis v. Brown*, 24-cv-1557-MJM; *AbbVie, et al. v. Brown*, No. 24cv-

1816-MJM, *PhRMA v. Brown*, 24-cv-1631-MJM; *AstraZeneca v. Brown*, 24-cv-1868-MJM;

- ***Missouri*:** *Novartix v. Bailey*, 24-cv-4131 (filed 8/2/24); *AbbVie, et al. v. Bailey*, 24-cv-996 (filed 7/22/24)

- ***West Virginia***: *PhRMA v. Morrisey*, No. 24-cv-271 (S.D. W.Va.); *Novartis v. Morrisey*, No. 24-cv-272 (S.D. W.Va.); *AbbVie, et al. v. Morrisey*, 24-cv-298

These cases were filed at various times and are at various stages of dispositive motion practice.

Relevant here, Arkansas, Mississippi, and Louisiana enacted legislation which do govern the distribution of 340B drugs to contract pharmacies by prohibiting the manufacturers from limiting covered entities' ability to contract with outside pharmacies.

- ***Arkansas*:** Arkansas passed Act 1103, Ark. Code Ann. § 23-92-604(c), "which applies to drug distribution agreements between manufacturers and covered entities in Arkansas. Act 1103 prohibits manufacturers from limiting covered entities' ability to contract with outside pharmacies." *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024).

- ***Louisiana*:** **"**In 2023, Louisiana enacted La. R.S. 40:2881 et seq. ("Act 358"), which prevents pharmaceutical companies from restricting contract pharmacy arrangements made by Section 340B covered entities." *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *2 (W.D. La. Sept. 30, 2024)

- ***Mississippi*:** Mississippi enacted H.B. 728, which requires manufacturers to deliver drugs ordered through the 340B program to for-profit contract pharmacies with which covered entities have arrangements under which the pharmacy will dispense discounted drugs to the covered entity's patients. *PhRMA v. Fitch*, No. 1:24-CV-160-HSO-BWR, 2024 WL 3277365, at *1 (S.D. Miss. July 1, 2024).

Because the 340B Program is silent about state regulations, Plaintiffs' challenges to similar legislation in other states have been squarely and soundly rejected. However, S.B. 28 does not address the price or volume at which a 340B drug can or must be sold nor does it address *distribution* of 340B drugs in Kansas or elsewhere. S.B. 28 appropriates money and directs the Attorney General to enforce the Kansas Consumer Protection Act (KCPA). Plaintiffs cannot, however, run afoul of S.B. 28 as that appropriation bill points to the KCPA and Plaintiffs do not allege that they are committing (or intend to commit) deceptive or unconscionable acts or practices

in violation of the KCPA. Hence, there is no standing, there is no case or controversy, and Plaintiffs fail to state a claim upon which relief may be granted.

## II. Statement of Facts

1. The Kansas Legislature approved SB 28 on April 5, 2024. Exhibit 1, Legislative History 2024 SB 28.

2. On April 15, 2024, SB 28 was enrolled and presented to Kansas Governor Laura Kelly. *Id.*

3. Governor Kelly approved SB 28 subject to line-item vetoes enumerated in a Message from the Governor Regarding Veto of SB 29. *Id.*, and Exhibit 2, SB-28-Line-Item-Veto-Signed-4.24.24.

4. SB 28 is entitled as follows:

> AN ACT making and concerning appropriations for the fiscal years ending June 30, 2024, June 30, 2025, June 30, 2026, June 30, 2027, and June 30, 2028, for state agencies; authorizing certain transfers, capital improvement projects and fees, imposing certain restrictions and limitations, and directing or authorizing certain receipts, disbursements, procedures and acts incidental to the foregoing; amending K.S.A. 2023 Supp. 2-223, 12-1775a, 12-5256, 65-180, 74-50,107, 74-8711, 74-99b34, 75- 6707, 76-775, 76-7,107, 79-2959, 79-2964, 79-3425i, 79-34,171 and 82a-955 and repealing the existing sections.

Exhibit 3, SB 28 as enrolled.

5. Section 1 of SB 28 provides as follows:

> (a) For the fiscal years ending June 30, 2024, June 30, 2025, June 30, 2026, June 30, 2027, and June 30, 2028, appropriations are hereby made, restrictions and limitations are hereby imposed, and transfers, capital improvement projects, fees, receipts, disbursements and acts incidental to the foregoing are hereby directed or authorized as provided in this act.
>
> (b) The agencies named in this act are hereby authorized to initiate and complete the capital improvement projects specified and authorized by this act or for which appropriations are made by this act, subject to the restrictions and limitations imposed by this act.
>
> (c) This act shall not be subject to the provisions of K.S.A. 75- 6702(a), and amendments thereto.

(d) The appropriations made by this act shall not be subject to the provisions of K.S.A. 46-155, and amendments thereto.

*Id.*, § 1.

6. SB 28 §§ 32(a)-(b) appropriate money to the Attorney General. or the fiscal year ending June 30, 2025. *Id*., § 32(a)-(b).

7. SB 28, § 32(g) and § 33 provide as follows:

(g) (1) During the fiscal year ending June 30, 2025, notwithstanding the provisions of Kansas consumer protection act, or any other statute to the contrary, in addition to the other purposes for which expenditures may be made by the above agency from moneys appropriated from the state general fund or any special revenue fund or funds for fiscal year 2025 by this or any other appropriation act of the 2024 regular session of the legislature, expenditures shall be made by the above agency from such moneys for fiscal year 2025 to enforce the provisions of the Kansas consumer protection act against a manufacturer that engages in the following actions:

(A) Deny, restrict, prohibit or otherwise interfere with the acquisition of a 340B drug by or delivery of a 340B drug to a pharmacy that is under contract with a 340B-covered entity and authorized under such contract to receive and dispense 340B drugs on behalf of the 340B=covered entity, unless such receipt and dispensing of 340B drugs by such pharmacy is prohibited by the United States department of health and human services; or

(B) interfere with a pharmacy that has a contract with a 340Bcovered entity.

(2) As used in this subsection:

(A) "340B-covered entity" means an entity that is participating in the federal 340B drug pricing program authorized by 42 U.S.C. § 256b, including such entity's pharmacy or pharmacies, or any pharmacy or pharmacies contracted for the purpose of dispensing drugs purchased through such program;

(B) "340B drug" means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to the federal 340B drug pricing program authorized by 42 U.S.C. § 256b and is purchased by a covered entity;

(C) "manufacturer" means the same as defined in K.S.A. 65-1626, and amendments thereto; and

(D) "pharmacy" means the same as defined in K.S.A. 65-1626, and amendments thereto.

Sec. 33. ATTORNEY GENERAL

> (a) (1) During the fiscal year ending June 30, 2026, notwithstanding the provisions of Kansas consumer protection act, or any other statute to the contrary, in addition to the other purposes for which expenditures may be made by the above agency from moneys appropriated from the state general fund or any special revenue fund or funds for fiscal year 2026 by this or any other appropriation act of the 2024 or 2025 regular session of the legislature, expenditures shall be made by the above agency from such moneys for fiscal year 2026 to enforce the provisions of the Kansas consumer protection act against a manufacturer that engages in the following actions:
>
> (A) Deny, restrict, prohibit or otherwise interfere with the acquisition of a 340B drug by or delivery of a 340B drug to a pharmacy that is under contract with a 340B-covered entity and authorized under such contract to receive and dispense 340B drugs on behalf of the 340Bcovered entity, unless such receipt and dispensing of 340B drugs by such pharmacy is prohibited by the United States department of health and human services; or
>
> (B) interfere with a pharmacy that has a contract with a 340Bcovered entity.
>
> (2) As used in this subsection:
>
> (A) "340B-covered entity" means an entity that is participating in the federal 340B drug pricing program authorized by 42 U.S.C. § 256b, including such entity's pharmacy or pharmacies, or any pharmacy or pharmacies contracted for the purpose of dispensing drugs purchased through such program;
>
> (B) "340B drug" means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to the federal 340B drug pricing program authorized by 42 U.S.C. § 256b and is purchased by a covered entity;
>
> (C) "manufacturer" means the same as defined in K.S.A. 65-1626, and amendments thereto; and
>
> (D) "pharmacy" means the same as defined in K.S.A. 65-1626, and amendments thereto.

*Id.*, § 32(g) and § 33.

## III. Argument and Authorities

### A. Standard of review.

Dismissal under Rule 12(b)(1) is appropriate if the Court lacks subject matter jurisdiction over claims asserted in the complaint. Dismissal under this provision is not a judgment on the merits of the action but rather a determination that the court lacks authority to adjudicate the matter. *See Castanedea v. INS*, 23 F.3d 1576, 1580 (10th Cir. 1994) (recognizing that the federal courts

are courts of limited jurisdiction and may exercise jurisdiction only where they specifically are authorized to do so).

Motions to dismiss brought under Rule 12(b)(1) "generally take one of two forms: (1) a facial attack on the sufficiency of the complaint's allegations as to subject matter jurisdiction; or (2) a challenge to the actual facts upon which subject matter jurisdiction is based." *Ruiz v. McDonnell*, 299 F.3d 1173, 1180 (10th Cir. 2002). If the motion is a facial challenge, the Court accepts the plaintiff's allegations as true. Id. Where the motion is brought as a factual attack, a court has "wide discretion to allow affidavits, other documents, and a limited evidentiary hearing to resolve disputed jurisdictional facts." *Holt v. United States*, 46 F.3d 1000, 1003 (10th Cir. 1995).

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter the pleadings are closed," but "early enough not to delay trial." Fed. R. Civ. P. 12(c). The standard for dismissal under Rule 12(c) is the same as a dismissal under Rule 12(b)(6). *Myers v. Koopman*, 738 F.3d 1190, 1193 (10th Cir. 2013). To survive a motion for judgment on the pleadings, the complaint must present factual allegations, assumed to be true, that "raise a right to relief above the speculative level," and must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). Judgment on the pleadings is appropriate when "the moving party has clearly established that no material issue of fact remains to be resolved and the party is entitled to judgment as a matter of law." *Sanders v. Mountain Am. Fed. Credit Union*, 689 F.3d 1138, 1141 (10th Cir. 2012) (citation omitted). Documents attached or referred to the pleadings may be considered in deciding a Rule 12(c) motion without converting the motion into one of summary judgment. *Park Univ. Enters., Inc. v. Am. Cas. Co.*, 442 F.3d 1239, 1244 (10th Cir. 2006); *Brokers' Choice of Am., Inc. v. NBC Universal, Inc.*, 861 F.3d 1081, 1103 (10th Cir. 2017). However, "the documents may only be considered to show their contents, not to prove the truth of matters asserted therein." *Tal*

*v. Hogan*, 453 F.3d 1244, 1265 (10th Cir. 2006).

While the court "must take all the factual allegations in the complaint as true," but is "'not bound to accept as true a legal conclusion couched as a factual allegation.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, the Court must first determine if the allegations are factual and entitled to an assumption of truth, or merely legal conclusions that are not so entitled. *Id*., at 679.

Summary judgment is appropriate if the moving party shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a) and (c). A factual dispute is "material" only if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). The pertinent facts here are found in the text of S.B. 28.

**B. Plaintiffs' claims must be dismissed for lack of subject matter jurisdiction.**

**1. Plaintiffs lack standing and there is no case or controversy.**

Article III of the United States Constitution restricts jurisdiction of the federal courts to adjudication of actual cases or controversies. *Utah Ass'n of Cntys. v. Bush*, 455 F.3d 1094, 1098 (10th Cir. 2006). "The federal courts are under an independent obligation to examine their own jurisdiction, and standing 'is perhaps the most important of [the jurisdictional] doctrines.'" *United States v. Hays*, 515 U.S. 737, 742 635 (1995) (alteration in original) (quoting *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 230–31 (1990)). Thus, the court has the obligation to satisfy itself as to jurisdiction at every stage of the proceeding without regard to whether it was raised by the parties. *Alexander v. Anheuser-Busch Cos., Inc*., 990 F.2d 536, 538 (10th Cir. 1993).

"The standing inquiry ensures that a plaintiff has a sufficient personal stake in a dispute to ensure the existence of a live case or controversy which renders judicial resolution appropriate." *Tandy v. City of Wichita*, 380 F.3d 1277, 1283 (10th Cir. 2004). To maintain suit in federal court, plaintiffs must demonstrate (1) injury, (2) caused by the conduct about which they complain, (3)

that is redressable. *Lujan v. Defnders of Wildlife*, 504 U.S. 555, 560–61 (1992). Standing is evaluated as of the time a case is filed and, if the case has progressed, "in light of all the evidence we now have." *Rio Grande Found. v. Oliver*, 57 F.4th 1147, 1161 (10th Cir. 2023).

The first element requires that plaintiffs suffered an injury in fact, which is an invasion of a legally protected interest that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Lujan*, 504 U.S. at 560. In a pre-enforcement constitutional challenge plaintiffs satisfy the injury-in-fact requirement if they show an intention to engage in conduct arguably affected with a constitutional interest but that the statute proscribes, and a credible threat of prosecution under the statute exists. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158-59 (2014); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007); *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979).

The second element for standing is causation—*i.e.*, whether the conduct complained of is fairly traceable to the challenged action of defendant, and not the result of independent action by some third party that is not before the Court. *Lujan*, 504 U.S. at 560.

The third element, redressability, requires that it be likely (not merely speculative) that decision favorable to plaintiff will redress their injury. *Id*. at 561. If, however, a separate statute not challenged by plaintiffs their conduct, decision for plaintiffs may not redress their alleged injury. *See Bishop v. Smith*, 760 F.3d 1070, 1078 (10th Cir. 2014) (injury not redressable when unchallenged legal obstacle is enforceable separately and distinctly from challenged provision).

All three elements for standing are lacking: (1) S.B. 28 does not cause any injury to Plaintiffs; (2) Plaintiffs do not allege the Attorney General has implemented any enforcement action under the auspices of S.B. 28 nor do they allege the Attorney General has threatened any enforcement action; and (3) Plaintiffs' alleged injury lies in the enforcement of the KCPA and not any substantive provision under S.B. 28.

**1. S.B. 28 appropriates money to the Attorney General to enforce the provisions of the KCPA. S.B. 28 does not substantively amend the KCPA and does not prohibit any act by a supplier nor does it require any act by a supplier.**

Attention must be paid to what S.B. 28 does and does not do. In short, S.B. 28 § 32 appropriates money to the Kansas Attorney General. Section 32(g) and § 33 direct the Attorney General to enforce the KCPA in fiscal years 2025 and 2026.

Plaintiffs allege S.B. 28 applies to pharmaceutical manufacturers. *24cv1111 Doc. 1*, ¶ 89 (citing S.B. 28, §§ 32, (g)(1)(A) and (B), 33); *24cv-4068 Doc. 1,* ¶ 44 (alleging "The statute addresses both acquisition and delivery."); *24cv1112 Doc. 1,* ¶ 51 (alleging S.B. 28 prohibits manufacturers from denying restricting prohibiting or interfering with acquisition or delivery of a 340B drug to a contract pharmacy); *24cv1132 Doc. 1*, ¶ 5 (alleging S.B. 28 "targets drug manufacturers in an effort to force them to provide 340B-priced drugs to an unlimited number of pharmacies"). The complaints go on to outline what plaintiffs claim S.B. 28 requires and/or prohibits, *see, e.g. 24cv1111 Doc. 1*, ¶¶ 90-97, but do so without remaining true to the text of the legislation. S.B. 28, § 32(a) appropriates money to the Attorney General. Sections 32(g) and 33(a) of S.B. 28 in provides that the Attorney General "in addition to the other purposes for which expenditures may be made" from the moneys appropriated for the 2025 and 2026 fiscal years "expenditures shall be made" by the Attorney General "to enforce the provisions of the Kansas consumer protection act against a manufacturer that engages in" actions enumerated in the § 32(g) and 33(a).[1]

The KCPA is found in K.S.A. 50-623 through K.S.A. 50-643. The purpose of the KCPA, in relevant part, is to "simplify, clarify and modernize the law governing consumer transactions" and "to protect consumers from suppliers ***who commit deceptive and unconscionable practices***."

[1] The full text of S.B. 28, § 32(g) and § 33 is set forth in § II, *supra*, ¶ 7. The enrolled bill is provided in Exhibit 3.

K.S.A. 50-623(a) and (b) (emphasis added). A "consumer" under the KCPA is "an individual, husband and wife, sole proprietor, or family partnership who seeks or acquires property or services for personal, family, household, business or agricultural purposes." K.S.A. 50-624(b). A "supplier" is "a manufacturer, distributor, dealer, seller, lessor, assignor, or other person who, in the ordinary course of business, solicits, engages in or enforces consumer transactions, whether or not dealing directly with the consumer." K.S.A. 50-624(l). A "consumer transaction" is "a sale, lease, assignment or other disposition for value of property … to a consumer; or a solicitation by a supplier with respect to any of these dispositions." K.S.A. 50-624(c). A "pharmacy" could conceivably be a "consumer" under the KCPA and a "manufacturer" could be a "supplier" under the KCPA. But application of the KCPA and S.B. 28 to Plaintiffs stops there. Plaintiffs do not allege they are committing (or intend to commit) deceptive and unconscionable practices under the KCPA. Absent a deceptive and unconscionable practice, the KCPA has no application to Plaintiff(s) and the appropriation of money to enforce the KCPA does not violate the rights of Plaintiffs.

Relevant here, the KCPA prohibits (1) deceptive acts and practices and (2) unconscionable acts or practices in connection with a consumer transaction. K.S.A. 50-626 and K.S.A. 50-627. Under K.S.A. 50-628, the attorney general is directed to enforce the KCPA throughout the state and receive and act on complaints. K.S.A. 50-632 permits the attorney general to enforce the KCPA. Remedies are available to the attorney general or any county or district attorney in an action for (1) declaratory judgment that an act or practice violates the KCPA, (2) injunctions or restraining orders against a supplier for violations of the KCPA, (3) recovery of damages on behalf of consumers for violations of the KCPA, and (4) recovery expenses and investigation fees. K.S.A. 50-632. The KCPA also permits aggrieved consumers to secure similar relief through private causes of action. K.S.A. 50-634. The KCPA permits civil penalties of up to $10,000 per violation.

K.S.A. 50-636.

Deceptive acts and practices, broadly speaking, involve knowing misrepresentations and false or misleading statements or communications. K.S.A. 50-626. Unconscionable acts and practices, broadly speaking involve

- taking advantage of the consumer unable to protect the consumer's interest though some infirmity, ignorance, illiteracy, language barrier to of an agreement or similar factor,
- price gouging;
- depriving the of the benefit of the bargain,
- inability of the to pay in full;
- excessively onesided transactions favoring the supplier;
- material misrepresentations;
- attempts to limit the implied warranties of merchantability and fitness for a particular purpose or any remedy provided by law for a breach of those warranties.

K.S.A. 50-627.

The KCPA neither requires Plaintiff Manufacturers to sell their product to any particular consumer nor does it forbid the sale of their product to any particular consumer. The denial, restriction, prohibition, or interference with the acquisition of a 340B drug by or delivery of a 340B drug to a pharmacy that is under contract with a 340B-covered entity is simply not part of the KCPA. ***If*** a manufacturer does deny, restricts, etc., such conduct does not, itself, violate the KCPA. Rather, the Attorney General is empowered only to enforce the KCPA throughout the state and receive and act on complaints, K.S.A. 50-628, through remedies afforded under K.S.A. 50-632. In any instance, such enforcement or action on a complaint must involve a deceptive act or practice and/or an unconscionable act or practice as defined in the KCPA. Merely being a manufacturer that sells and/or delivers a 340B drug cannot subject a plaintiff to action under the KCPA.

The complaint is devoid of allegations that Plaintiff(s) are subject to an enforcement action under the KCPA for any deceptive and/or unconscionable practice. Instead, Plaintiffs allege:

> S.B. 28 broadly prohibits manufacturers and distributors from interfer[ing] with a pharmacy that has a contract with a 340Bcovered entity. S.B. 28, §§ 32 (g)(1)(B),

> 33. It further prohibits manufacturers and distributors from 'deny[ing], restrict[ing], prohibit[ing] or otherwise interfer[ing] with the acquisition of a 340B drug … .

*24cv1111 Doc. 1*, ¶ 8. *See also id.*, ¶ 26 (alleging the Attorney General "has the responsibility and authority to enforce the laws of the State of Kansas, including S.B. 28, which makes any violation a violation of the state's Consumer Protection Act.").

***Not so***. These conclusory allegations are not entitled to deference on a motion under Rule 12(b) or (c). "Conclusory allegations are not entitled to the assumption of truth." *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021). Rather, the court is to disregard conclusory statements and look instead to factual allegations to determine whether Plaintiffs stated a plausible claim. *Id*. "[A] complaint must contain sufficient factual matter ... to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). No language in the S.B. 28 or the KCPA prohibits manufacturers and distributors from interfering with a pharmacy that has a contract with a 340B covered entity nor does any text prohibit manufacturers and distributors from denying, restricting, prohibiting or otherwise interfering with the acquisition of a 340B drug.

Plaintiffs contend S.B. 28 "purports to require AbbVie to provide its 340B discounted drugs—its property—to an unlimited number of for-profit commercial pharmacies, or be subject to the penalties available to the Attorney General pursuant to the Kansas Consumer Protection Act." *Doc. 1*, ¶ 96. Again, not so. No such language is found in the KCPA nor can any allegation in the complaint be construed to conclude a manufacturer is compelled by the KCPA to provide a 340B discounted drug to <u>any</u> consumer, let alone an unlimited number of consumers.

As it relates here, the relevant factual allegations point to the text of S.B. 28. From the text of the legislation, the Court can adjudge and dismiss Plaintiff's claims. S.B. 28 does not require anything of a drug manufacturer nor does it prohibit or forbid anything. S.B. 28 appropriates money to the Attorney General's Office and directs the Attorney General to enforce the KCPA

against manufacturers that deny, restrict, prohibit or otherwise interfere with the acquisition or delivery of a 340B drug. Such denial, restriction, prohibition, or other interference may or may not violate the KCPA, but there must be an underlying KCPA violation and S.B. 28 does not define the violation. Plaintiffs do not allege that plaintiffs are presently violating KCPA (either by committing deceptive acts and practices prohibited under K.S.A. 50-626 or unconscionable acts and practices prohibited under K.S.A. 50-627). Nor do plaintiffs allege they have any intention of violating the KCPA in the future.

When interpreting a term in a statute, the court first examines "the plain language of the text, giving each word its ordinary and customary meaning." *Mitchell v. C.I.R.*, 775 F.3d 1243, 1249 (10th Cir. 2015). Terms are afforded their plain and ordinary meaning and are applied as written, considering the broader context of the statute as a whole. *Conrad v. Phone Directories Co., Inc*., 585 F.3d 1376, 1381 (10th Cir. 2009). Only if a statute is ambiguous, does the Court turn to and apply canons of construction as rules of thumb to aid in interpretation. *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253-54 (1992).

A plain reading of the KCPA and S.B. 28 §§ 32(g) and 33(a) reveal the KCPA does not empower the Attorney General to

- Take property for private benefit;
- Take property without just compensation;
- Require the sale of goods or property;
- Forbid the sale of goods of property (in the absence of violations of the KCPA);
- Control the means of delivery of a 340B drug.

In short, S.B. 28 (1) does not empower the Attorney General to do anything other than expend appropriated monies, (2) does not prohibit any act or conduct by a manufacturer and (3) does not require any conduct by a manufacturer.

**C. Takings claim. *Abbvie* Count I and *AstraZeneca* Count IV. S.B. 28 does not constitute a taking in violation of the Takings Clause.**

Plaintiffs allege:

> S.B. 28 appropriates AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies. If Kansas requires manufacturers to provide their drugs to other private entities at below-market prices—by purporting to add S.B. 28 does not constitute a taking in violation of the Takings Clause that as a state-law obligation attached to the federal 340B scheme—then Kansas is engaged in an impermissible per se violation of the Constitution's Takings and Due Process Clauses.

*24cv1111 Doc. 1,* ¶ 113. *See also 24cv1112 Doc. 1,* ¶ 94 (alleging "SB 28 takes the private property of manufacturers" for private use). Plaintiffs argue, in the alternative, S.B. 28 effectuates a partial regulatory taking under *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 124 (1978). *24cv1111 Doc. 1,* ¶¶ 115-116 (S.B. 28's purported requirement that manufacturers transfer their drugs to commercial pharmacies is constitutionally impermissible ….")

S.B. 28 does not require a transfer of the Plaintiffs' drugs to commercial pharmacies. S.B. 28 appropriates money to the Attorney General to enforce the KCPA. The KCPA does not require a transfer of the Plaintiffs' drugs to commercial pharmacies. Rather, it prohibits deceptive and unconscionable acts and practices.

The Fifth Amendment of the U.S. Constitution provides that the federal government may not "directly appropriate[] private property for its *own* use*." Tahoe–Sierra Preservation Council, Inc. v. Tahoe Regional Planning Agency*, 535 U.S. 302, 324 (2002) (emphasis added); *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015). This same concept is applied to the States through the Fourteenth Amendment. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 536 (2005). Under the Takings Clause of the Fifth Amendment, "private property" shall not "be taken for public use, without just compensation." U.S.CONST. amend. V.

Takings claims are recognized as to both personal property, including goods, and real property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015). A taking can be either per se or regulatory, both of which entitle the property owner to just compensation. *Cedar Point Nursey v. Hassid*, 594 U.S. 139, 147–49 (2021). A per se taking occurs "[w]hen the government physically

acquires private property for a public use," including "when the government physically takes possession of property without acquiring title to it." *Id*. at 147.

A taking can also occur as a result of "the deprivation of the former owner rather than the accretion of a right or interest to the sovereign." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005–06 (1984) (internal quotation marks and citation omitted). The Supreme Court has held that a regulatory taking occurs when a regulation "goes too far" in limiting an owner's use of her property. *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922).

To determine whether a regulation amounts to a taking, courts apply the test developed in *Penn Central Transportation Company v. City of New York*, 438 U.S. 104 (1978). The *Penn Central* test requires "balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action." *Id*. A regulation that deprives a property owner of "***all*** economically beneficial uses" of her property constitutes a regulatory taking. *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019–20 (1992) (emphasis in original) (finding a regulatory taking, and thus requiring just compensation, when enforcement of a "coastal-zone construction ban" rendered beachfront property "valueless").

Without regard to payment of just compensation for a taking, property may only "be taken for public use." U.S. Const. Amend. V. The phrase "public use" requires that the taking "serve[ ] a 'public purpose.'" *Kelo v. New London*, 545 U.S. 469, 480 (2005). "Public purpose" is a broadly defined concept that reflects the Supreme Court's "longstanding policy of deference to legislative judgments" in redevelopment of property, and in "a purely economic context" as well. *Id*. at 480–82.

When private parties, voluntarily, accept responsibilities under federal law there is no taking. where a service provider voluntarily participates in a price-regulated program or activity,

there is no legal compulsion to provide service and thus there can be no taking. *Bowles v. Willingham*, 321 U.S. 503, 517–18 (1944); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *Burditt v. United States Dep't of Health and Human Servs.*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Department of Public Welfare*, 742 F.2d 442, 446 (1984), *cert. denied*, 469 U.S. 1215 (1985). Government regulation affecting a group's property interests is not a taking when the regulated group is not required to participate in the regulated industry or program. *Burditt*, 934 F.2d 1376. Thus, a "state law limiting fees that nursing homes voluntarily participating in Medicaid may charge non-Medicaid patients effects no taking '[d]espite the strong financial inducement to participate in Medicaid.'" *Id*. (quoting *Minnesota Ass'n of Health Care Facilities, Inc*., 742 F.2d at 446).

Plaintiffs' characterization of S.B. 28 as compelling direct, confiscatory sales to private pharmacies misses the mark. As discussed above, S.B. 28 does not compel anything, and certainly does not compel sales of 340B drugs to contract pharmacies. Discounted drugs are sold to covered entities under the terms and conditions of the PPAs and the Section 340B program—they are not sold to pharmacies that enter into contracts to dispense the drugs on behalf of covered entities. *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *13–14 (W.D. La. Sept. 30, 2024).

Plaintiffs' argument here—that an unconstitutional private taking occurs when the government requires that a drug company transfer its drugs to contract pharmacies as a condition of obtaining coverage of its drugs under federal health insurance programs—has been rejected elsewhere and should be rejected here as well. *Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs*., No. 121CV00081SEBMJD, 2021 WL 5039566, at *21 (S.D. Ind. Oct. 29, 2021) (participation in 340B program is voluntary and a manufacturer is free to terminate participation which forecloses a takings claim); *PhRMA v. Murrill*, 2024 WL 4361597, at *15 (same); *AbbVie*

*Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965, at *16-*20 (S.D. Miss. July 22, 2024) (same).

**D. S.B. 28 is not preempted by 340B or federal patent law.**

The Supremacy Clause provides the laws of the United States "shall be the supreme Law of the Land" binding upon on the States "any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. Art. VI, cl. 2; ). A "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Grp., Inc*., 505 U.S. 504, 516 (1992). Thus, "Congress may ... pre-empt, i.e., invalidate, a state law through federal legislation." *Oneok, Inc. v. Learjet*, Inc., 575 U.S. 373, 376 (2015). "But even where, as here, a statute does not refer expressly to pre-emption, Congress may implicitly pre-empt a state law, rule, or other state action." *Id*. Where preemption is alleged, "'[t]he purpose of Congress is the ultimate touchstone' of pre-emption analysis." *Cipollone*, 505 U.S. at 516 (quoting *Malone v. White Motor Corp*., 435 U.S. 497, 504 (1978)).

**1. 340B preemption—*Abbvie* Count II; *AstraZeneca* Count I; *Novartis* Count 1; *PhRMA* Count I. Congress has not expressly or impliedly preempted state regulation of the delivery of 340B drugs.**

Courts have identified at least three types of preemption: (1) express preemption, (2) field preemption, and (3) conflict or obstacle preemption. *See, e.g., English v. Gen. Elec. Co.*, 496 U.S. 72, 78 (1990). Noting that, first, Congress can explicitly pre-empt state law. *Id*. Second, absent explicit statutory language expressing preemption, "state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id*. at 79. Conflict/obstacle preemption exists when to the extent a state law "actually conflicts with federal law" such that "it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id*. (quotations and citation omitted). *See also Oneok,*

*Inc*., 575 U.S. at 377 (Congress may impliedly preempt state law "either through 'field' pre-emption or 'conflict' preemption."). Plaintiffs do not invoke express preemption but invoke both field and conflict/obstacle preemption. *Doc. 1,* ¶¶ 120, 123. Neither applies.

Analysis of a preemption claim "'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by … Federal Act unless that [is] the clear and manifest purpose of Congress.'" *Cipollone*, 505 U.S. at 516 (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947)). There is a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause." *Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc*., 471 U.S. 707, 715 (1985).

The gravamen of Plaintiffs' 340B field preemption arguments is that the Section 340B program is such that Congress left no room for states to exercise its regulatory powers with respect to contract pharmacies. *AbbVie 24cv1111 Doc. 1,* ¶¶ 97, 101, 120, 123-126; *AstraZeneca 24cv1112 Doc. 1,* ¶¶ 64, 70-76, 110-113; *Novartis, 24cv4068 Doc. 1,* ¶¶ 2, 54-65; *PhRMA 24cv1132 Doc. 1,* ¶¶ 100-114. Substantially similar claims have been raised and disposed of elsewhere. *See, e.g., PhRMA v. McClain*, 95 F.4th 1136, 1140 (8th Cir. 2024), *petition for cert. filed* (No. 24-118 Aug. 2, 2024) (Arkansas statute prohibiting drug manufacturers from limiting covered entities' ability to contract with outside pharmacies not preempted by 340B Program on field or conflict preemption theories); *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *8-*9 (W.D. La. Sept. 30, 2024) (similar Louisiana statute are not preempted by 340B Program on field or conflict preemption theories); *Novartis Pharms. Corp. v. Fitch*, No. 1:24-CV-164-HSO-BWR, 2024 WL 3276407, at *5-*9 (S.D. Miss. July 1, 2024) (Mississippi statute are not preempted by 340B Program on field or conflict preemption theories); *AbbVie Inc. v. Fitch*, No. 1:24-CV-184-HSO-BWR, 2024 WL 3503965, at *8-*16 (S.D. Miss. July 22, 2024) (same).

The statutory text governing the 340B program does not support a field preemption claim.

The regulatory and enforcement framework focuses on participating pharmaceutical companies and certain "covered entities" defined and delineated in the governing statutes and regulations. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5). Under the 340B program, companies wishing to participate in the Medicare or Medicaid program must enter into written agreements with HHS to provide discounted prices "for covered outpatient drugs purchased by a covered entity." 42 U.S.C. § 1396r-8(a); 42 C.F.R. Part 10 §§ 10.2, 10.3. These "covered entities" are health care providers who providing, generally, services to low-income and rural patients. *Astra USA, Inc. v. Santa Clara County*,, 563 U.S. 110, 115 (2011); 42 C.F.R. Part 10 § 10.3. While the law defines which health care providers qualify as "covered entities" eligible to receive discounted drugs under the Section 340B program, 42 U.S.C. § 256b(a); *Astra USA*, 563 U.S. at 115, the law restricts covered entities from receiving the duplicate discounts. 42 U.S.C. § 256b(a)(5)(A)(i). The law also prevents "diversion" of 340B drugs, requiring that that covered entities receiving discounted drugs provide them only to their patients. 42 U.S.C. § 256b(a)(5)(B). The federal statutory scheme provides enforcement mechanisms to ensure compliance. See, e.g., 42 U.S.C. § 256b(d); 42 C.F.R. §§ 10.10, 10.20 - 10.25.

Section 340B is, however, "silent with respect to the role of pharmacies who enter into contracts with covered entities to receive and dispense discounted drugs under Section 340B." *PhRMA v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597, at *5. "The statute does not mention contract pharmacies in defining the health care providers qualified as "covered entities," nor does it refer to contract pharmacies in delineating the obligations of participating pharmaceutical companies with respect to covered entities." *Id.*

Plaintiffs mischaracterize S.B. 28 when claiming an appropriations bill compels drug manufacturers to sell drugs to contract pharmacies at 340B prices. S.B. 28 contains no such language. S.B. 28 does not make a "contract pharmacy" a "covered entity." "Section 340B does

not prevent covered entities from entering into contracts with independent pharmacies, but these contract pharmacies are not 'covered entities' …." *PhRMA v. Murrill*, 2024 WL 4361597, at *5. Plaintiff's field preemption arguments overstate the extent which the federal government occupies the field with respect to covered health care providers and their contract pharmacies. *PhRMA v. McClain*, 95 F.4th at 1143; *PhRMA v. Murrill*, 2024 WL 4361597, at *6.

Plaintiffs contend conflict preemption applies under in *Sanofi Aventis U.S. LLC (Sanofi) v. U.S. Dep't of Health and Human Services*, 58 F.4th 696 (3d Cir. 2023). Conflict/obstacle preemption fails for same reasons field preemption fails. The 340B program does not address contract pharmacies. Thus, S.B. 28's reference to "pharmacy or pharmacies contracted for the purpose of dispensing drugs purchased through" a 340B program does not conflict with § 340B. *Sanofi* is fatal to a conflict preemption claim because "if Section 340B does not address contract pharmacies or the relationship between covered entities and their contract pharmacies, a state statute that specifically addresses contract pharmacies cannot conflict with Section 340B." *PhRMA v. Murrill*, 2024 WL 4361597, at *8. *See also PhRMA v. McClain*, 95 F.4th at 1145.

**2. Patent and drug exclusivity preemption; *AstraZenea* Count II, *Novartis* Count II. Patent law does not expressly or impliedly preempt S.B. 28.**

The *AstraZeneca* and *Novartis* Plaintiffs also assert conflict/obstacle preemption based on federal patent law. This claim fails because nothing in S.B. 28 conflicts with federal patent laws.

Federal patent law preempts state law claims only to the extent that state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' in enacting the patent laws." *In re Effexor Antitrust Litig.*, 337 F. Supp.3d, 435, 448 (D.N.J. 2018), quoting *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). The essential criteria for determining whether a state law is preempted are the objectives of the federal patent laws. *Biotech. Indus. Org. (BIO) v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007) (holding federal patent law preempted the District of Columbia's Prescription Drug Excessive Pricing Act of 2005

because the "underlying determination about the proper balance between innovators' profit and consumer access to medication ... is exclusively one for Congress to make," and the local law stood "as an obstacle to the federal patent law's balance of objectives"). The fundamental goal of the patent law is spelled out in the Constitution: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id.* (citing U.S. Const. art. I, § 8, cl. 8).

> Inventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected "exclusive right" to exclude others from making, using, or selling embodiments of their invention. Patentees value the right to exclude in part because the ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent's term.

*BIO*, 496 F.3d at 1372

> [T]he Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

*King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed.Cir. 1995).

Federal patent law does not, however, permit "a patent holder to commit unfair and deceptive practices that violate state consumer protection laws—simply because it owns patent rights." *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig*., 336 F. Supp. 3d 1256, 1333–34 (D. Kan. 2018).

> [F]ederal patent law does not preempt state consumer protection claims when a state law claim " 'address[es] entirely different wrongs[,]' 'provide[s] different forms of relief,' and 'is not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law.' "

*In re Loestrin 24 Fe Antitrust Litig.*, 261 F.Supp.3d 307, 357 (D.R.I. 2017) (quoting *Dow Chem. Co. v. Exxon Corp*., 139 F.3d 1470, 1478 (Fed. Cir. 1998)). *See also Picone v. Shire PLC*, No. 16-cv-12396-ADB, 2017 WL 4873506, at *14 (D. Mass. Oct. 20, 2017) (denying portion of Rule 12(b)(6) motion seeking dismissal of state consumer protection and antitrust law claims based on

preemption because those claims "are based on tortious conduct in the marketplace—*i.e.*, the purportedly illegal settlement agreements—that require different elements than any arguably corresponding federal patent law claim (such as patent invalidity), and are therefore not protected or governed by federal patent law"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F.Supp.3d at 357 (holding on a Rule 12(b)(6) motion to dismiss that federal patent law did not preempt plaintiffs' state consumer protection law claims because plaintiffs alleged that defendants enforced their patent in the marketplace with bad faith); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F.Supp.2d 198, 224 (S.D.N.Y. 2012) (holding on a Rule 12(b)(6) motion that the patent laws didn't preempt plaintiffs' state consumer protection law claims because plaintiffs alleged other "wrongful conduct in the marketplace" to support the claims such as "an invalid Orange Book listing, sham patent infringement litigation, and a sham citizen petition").

S.B. 28 does not, on its face, target patent rights or, by its terms, apply only to patented drugs or the price of patented drugs. Nor does the KCPA. Thus, Plaintiff's fail to state a conflict preemption claim based on federal patent law. *See PhRMA v. Murrill*, 2024 WL 4361597, at *9; *Novartis Pharms. Corp. v. Fitch*, 2024 WL 3276407, at *10.

**E. Due Process Clause void for vagueness, Fourteenth Amendment. *AbbVie* Count III; *PhRMA* Count III. S.B. 28 is not void for vagueness.**

Plaintiff claims S.B. 28 is unconstitutionally vague and, therefore, violates the Due Process Clause of the Fourteenth Amendment. S.B. 28 does not prohibit or penalize conduct, neither does the appropriations bill deprive plaintiff of their rights.

A statute may be challenged as vague in two ways; First, a plaintiff may challenge the statute as vague as applied to his particular circumstances, *See Galbreath v. City of Oklahoma City*, 568 Fed.Appx. 534, 539 (10th Cir. 2014), or second, a plaintiff may make a facially vague challenge. *See Dr. John's, Inc. v. City of Roy,* 465 F.3d 1150, 1157 (10th Cir. 2006). A law is unconstitutionally vague when it: "(1) fails to apprise persons of ordinary intelligence of the

prohibited conduct, or (2) encourages arbitrary and discriminatory enforcement." *City of Chicago v. Morales*, 527 U.S. 41, 90 (1999). Mere imprecision does not render a statute vague. *Ferguson v. Estelle*, 718 F.2d 730, 735 (5th Cir. 1983). In fact, "[a] facial challenge for vagueness is appropriate only on an allegation that the law is vague not in the sense that it requires a person to conform his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all." *Id*. (quoting *Coates v. Cincinnati*, 402 U.S. 611, 614 (1971)).

Plaintiffs claim SB 28 prohibits them from "interfering" with contract pharmacies while providing no fair warning as to what conduct is actually prohibited. As discussed above, S.B. 28 does not prohibit any conduct. Rather, S.B. 28 directs the Attorney General to enforce the KCPA.

The constitutionality of a statute will be presumed, if there is any reasonable way to construe the statute as constitutionally valid, that should be done. A statute should not be stricken down unless the infringement of the superior law is clear beyond a substantial doubt. *Moody v. Board of Shawnee County Comm'rs*, 237 Kan. 67, 697 P.2d 1310 (1985); *City of Wichita v. Wallace*, 246 Kan. 253, 257 (1990). After such a claim is raised, the court will look to (1) whether the ordinance gives fair warning to those persons potentially subject to it; and (2) whether the ordinance adequately guards against arbitrary and discriminatory enforcement. *Wallace* at 259.

Vagueness challenges "are greeted with a strong presumption in favor of the statute's validity." *See Schrag v. Dinges*, 788 F. Supp. 1543, 1553 (D. Kan. 1992) (citing *United States v. National Dairy Prods. Corp.,* 372 U.S. 29, 32 (1963)). A statute which is so vague when persons of common intelligence must necessarily guess at its meaning and differ as to its application violates due process." *Brennan v. Occupational Safety and Health Review Comm'n*, 505 F.2d 869, 872 (10th Cir. 1974). "The void-for-vagueness doctrine reflects the principle that a statute which either forbids or requires doing of an act in terms so vague persons of common intelligence must

necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law." *Roberts v. U.S. Jaycees,* 468 U.S. 609, 629 (1984). The requirement that government articulate its aims with a reasonable degree of clarity ensures that state power will be exercised only on behalf of policies reflecting an authoritative choice among competing social values, reduces the danger of caprice and discrimination in the administration of the laws, enables individuals to conform their conduct to the requirements of law, and permits meaningful judicial review. *Id*. And when speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253–54 (2012).

A facial challenge fails, in part, because S.B. neither proscribes nor requires any conduct. For an as-applied vagueness challenge, the analysis must be tethered to the factual context in which the law was applied. *United States v. Franklin-El*, 554 F.3d 903, 910 (10th Cir. 2009) ("Because this is an as-applied challenge, we consider this statute in light of the charged conduct."). Here, there is no application of S.B. 28 as the Attorney General can take action only if there is a KCPA violation—i.e., conduct amounting to a deceptive and/or unconsciounable act or practice. A law that does not reach constitutionally protected conduct" is not "unduly vague, in violation of due process," unless "the complainant [can] demonstrate that the law is impermissibly vague in all of its applications." *Vill. of Hoffman Ests. v. Flipside*, *Hoffman Estates, Inc.* 455 U.S. 489, 497 (1982). "The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Id*. at 498. A plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others. *Id*. at 495.

"[E]conomic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior

carefully, can be expected to consult relevant legislation in advance of action." *Id*. at 498. (citation omitted). The Supreme Court "has also expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe," though "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." *Id*. at 498–99.

In settling on a fair reading of a statute, it is not unusual to consider the ordinary meaning of a defined term, particularly when there is tension between that ordinary meaning and the reach of the definition. *Bond v. U.S.*, 572 U.S. 844, 861 (2014). While courts should interpret a statute with an eye to the surrounding landscape and an ear for harmonizing potentially discordant provisions, these guiding principles are not substitutes for lawmaking. *Zaimi v. U.S.*, 476 F.2d. 511, 523 (D. C. Cir. 1973) S.B. 28 does not make plaintiffs more or less susceptible to scrutiny under the KCPA. While S.B. 28 does not define the term "interfere." The verb "interfere" means "to interpose in a way that hinders or impedes." "interfere," Merriam-Webster.com Dictionary, https://www.merriam-webster.com/dictionary/interfere. Accessed 10/31/2024. "[T]he term 'interfere as used in Act 358 should be construed as proscribing actions that prevent or hinder the acquisition or delivery of Section 340B drugs to contract pharmacies" *PhRMA v. Murrill*, 2024 WL 4361597, at *10. "Considering the definition of "interfere" and its textual context in Act 358, the term is sufficiently definite to provide notice of the conduct proscribed and to prevent arbitrary or discriminatory enforcement …." *Id.* Further. S.B. 28 itself creates no substantive prohibition or requirement but instead S.B. 28 directs the Attorney General to enforce the KCPA which has its own definitions, prohibitions and proscriptions.

In short, S.B. 28 is not void for vagueness either facially or as-applied.

**F. Due Process, Kansas Constitution, void for vagueness. *AbbVie Count IV*.**

The foregoing analysis is equally dispositive of the due process claims under the Kansas

Constitution. The Kansas Constitution Bill of Rights, sections 1 and 2 offer the same guarantees of due process as provided in the Fourteenth Amendment of the United States Constitution. *Farley v. Engelken*, 241 Kan. 663, 667, 740 P.2d 1058 (1987) (Sections 1 and 2 of the Kansas Constitution Bill of Rights "are given much the same effect as the clauses of the Fourteenth Amendment relating to due process and equal protection of the law."); *Rivera v. Schwab*, 315 Kan. 877, 893, 512 P.3d 168 (2022), *cert. denied*, 143 S. Ct. 1055 (2023).

**G. One-Subject Rule under the Kansas Constitution. *AbbVie* Count V; *AstraZeneca* Count V. S.B. 28 does not violate the one-subject rule.**

Article 2, § 16 of the Kansas Constitution, is also known as the one-subject rule. *Kansas One–Call System v. State*, 294 Kan. 220, 226 (2012). The rule provides:

> No bill shall contain more than one subject, except appropriation bills and bills for revision or codification of statutes. The subject of each bill shall be expressed in its title. No law shall be revived or amended, unless the new act contain the entire act revived or the section or sections amended, and the section or sections so amended shall be repealed. The provisions of this section shall be liberally construed to effectuate the acts of the legislature.

*Id*. (citing Article 2, § 16)

The purpose of the one-subject rule is to prevent legislative abuses such as "logrolling," a situation in which several legislators combine their unrelated proposals and present them as separate provisions of one bill. *Id*. In that situation, a bill is able to pass by virtue of the combined votes of the separate factions, with the perceived evil being a measure can pass which, standing alone, would have been defeated. *Id*. A 1974 amendment made important changes to the one-subject rule. *Id*.

> First, the amendment added an exception for appropriation bills. Second, it added the liberal interpretation clause. This clause states: "The provisions of the section shall be liberally construed to effectuate the acts of the legislature." Under this statutory rule of construction, courts construe the statute to affect the beneficial purpose of the statute.

*Id.* "[A] statute does not violate the single-subject rule unless 'invalidity is manifest.'" *KPERS v.*

*Reimer & Koger Assocs., Inc.*, 262 Kan. 635, 676, 941 P.2d 1321 (1997). Legislation is valid under the one-subject rule "so long as the provisions of the bill are 'all germane to the subject expressed in the title,' and will be invalidated only where 'an act embraces two or more dissimilar and discordant subjects that cannot reasonably be considered as having any legitimate connection with or relationship to each other. [Citation omitted.]" *Id.*

Courts should be only concerned with the legislative power to enact statutes, not with the wisdom behind those enactments. *KNEA v. State*, 305 Kan. 739, 749, 387 P.3d 795 (2017). "Article 2, § 16 commands courts that '[t]he provisions of this section shall be liberally construed to effectuate the acts of the legislature. *Id*. (quoting Article 2, § 16). The subject of a bill

> may include innumerable minor subjects, provided all these minor subjects are capable of being so combined as to form only one grand and comprehensive subject; and, if the title to the bill containing this grand and comprehensive subject is also comprehensive enough to include all these minor subjects as one subject, the bill, and all parts thereof, will be valid.

*State ex rel. Fatzer v. Shanahan*, 178 Kan. 400, 403, 286 P.2d 742 (1955) (quoting *Division of Howard Co*., 15 Kan. 194, Syl. ¶ 4 [1875]).

SB 28 is an omnibus appropriations bill, "Making and concerning supplemental appropriations for fiscal years 2024 and 2025 and appropriations for fiscal years 2025, 2026, 2027 and 2028 for various state agencies." S.B. 28, preamble. The challenged portion of the bill appropriates funds to the Attorney General and, *inter alia,* directs enforcement of the KCPA. S.B. 28 has but a single subject—appropriations. There is no violation of the one-subject rule.

**H. Contracts Clause. *AstraZeneca* Count III. S.B. 28 does not violate the Contracts Clause.**

The Contracts Clause prohibits States from passing laws "impairing the Obligation of Contracts." U.S. CONST. art. I, § 10. The Supreme Court's current two-step analysis for Contracts Clause challenges requires that a court first determine whether the state law at issue substantially impairs a contractual relationship, and if so, whether it does so for a legitimate purpose. *Ashley*

*Sveen v. Kaye Melin*, 584 U.S. 811, 819 (2018).

> [N]ot all laws affecting pre-existing contracts violate the Clause. *See El Paso v. Simmons*, 379 U.S. 497, 506–507 (1965). To determine when such a law crosses the constitutional line, this Court has long applied a two-step test. The threshold issue is whether the state law has "operated as a substantial impairment of a contractual relationship." *Allied Structural Steel Co*., 438 U.S., at 244. In answering that question, the Court has considered the extent to which the law undermines the contractual bargain, interferes with a party's reasonable expectations, and prevents the party from safeguarding or reinstating his rights. *See id*., at 246; *El Paso*, 379 U.S., at 514–515; *Texaco, Inc. v. Short*, 454 U.S. 516, 531 (1982). If such factors show a substantial impairment, the inquiry turns to the means and ends of the legislation. In particular, the Court has asked whether the state law is drawn in an "appropriate" and "reasonable" way to advance "a significant and legitimate public purpose." *Energy Reserves Group, Inc. v. Kansas Power & Light Co*., 459 U.S. 400, 411–412 (1983).

*Id*. As an initial matter, S.B. 28 does not substantially impair a contractual relationship. S.B. 28 appropriates money and directs the Attorney General to expend *some* of the appropriated money enforcing the KCPA.

AstraZeneca contends S.B. 28 impairs contractual relationships. *22cv1112 Doc. 1, ¶ 85.* ("the 340B program operates through contracts, which are called pharmaceutical pricing agreements (PPAs)"). AstraZeneca alleges it "joined the 340B program with the expectation and understanding that it would be required to provide discounted drugs to only a limited number of covered entities." *Id.*, ¶ 86. S.B. 28 does nothing to expand or contract the number of covered entities with which AstraZeneca may or must contract. *PhRMA v. Murrill*, 2024 WL 4361597, at *12 ("does not expand or otherwise enlarge the beneficiaries of the Section 340B program").

First, S.B. 28 imposes no substantive requirements on AstraZeneca or any other manufacturer. Second, S.B. 28 directs the attorney general to enforce the KCPA's prohibitions on deceptive or unconscionable acts or practices against a manufacturer that is denying, restricting, prohibiting otherwise interfering with the acquisition or delivery of a 340B drug to a contract pharmacy under contract with a 340B-covered entity to receive and dispense 340B drugs on behalf of the covered entity. Even if S.B. 28 imposes the prohibitions alleged by Plaintiff, "the terms of

the PPA remain unchanged" and "does not void any contracts." *See, e.g., PhRMA v. Murrill*, 2024 WL 4361597, at *12. Further, "[e]ven if the Court were to find that [the Act] somehow impairs AstraZeneca's PPA by preventing restrictions on contract pharmacies, the State would have a legitimate purpose for doing so." *Id.,* *13. "The state could credibly argue that Act 358 promotes greater access to discounted drugs by preventing restrictions on the distribution of those drugs through multiple contract pharmacies." *Id.* "The drug industry is a 'pervasively regulated business." [Citation omitted.] Since AstraZeneca can reasonably expect regulation with respect to the sale of drugs and, especially with respect to its voluntary participation in federal benefit programs such as Medicaid and Medicare, its claim 'fails at the threshold question for proving a modern Contracts Clause violation.' [Citation omitted.]" *Id.*

S.B. 28 does not violate the Contracts Clause. Defendant is entitled to judgment as a matter of law.

## IV. Conclusion

For the foregoing reasons, Defendant is entitled to judgment as a matter of law as to all claims asserted.

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