2022 IL App (4th) 210325

NO. 4-21-0325

IN THE APPELLATE COURT

OF ILLINOIS

FOURTH DISTRICT

FILED
November 23, 2022
Carla Bender
4th District Appellate
Court, IL

X-GEN PHARMACEUTICALS, INC., Plaintiff-Appellant, v. THE DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION; BRYAN A. SCHNEIDER, in His Official Capacity as Secretary of Financial and Professional Regulation; and JESSICA A. BAER, in Her Official Capacity as Director of the Division of Professional Regulation of the Department of Financial and Professional Regulation, Defendants-Appellees.	)	Appeal from the Circuit Court of Sangamon County No. 18MR821 Honorable Christopher G. Perrin, Judge Presiding.

JUSTICE TURNER delivered the judgment of the court, with opinion.
Presiding Justice Knecht and Justice Bridges concurred in the judgment and opinion.

OPINION

¶ 1 In October 2018, plaintiff, X-Gen Pharmaceuticals, Inc., filed a complaint for administrative review against defendants, the Department of Financial and Professional Regulation (Department); Bryan A. Schneider, in his official capacity as Secretary of the Department; and Jessica A. Baer, in her official capacity as director of the division of Professional Regulation of the Department (Director). Plaintiff sought review of the Director's September 17, 2018, order, imposing a $1500 fine on plaintiff. In June 2019, the Sangamon County circuit court dismissed with prejudice plaintiff's complaint. Plaintiff appealed, and this court reversed the dismissal and remanded the cause for further proceedings. *X-Gen Pharmaceuticals, Inc. v. Department of Financial & Professional Regulation*, 2020 IL App (4th) 190657-U. On remand,

the circuit court held a hearing on plaintiff's petition for administrative review and denied the petition.

¶ 2 Plaintiff again appeals and asserts the Department's authority to impose reciprocal discipline is preempted by federal law. We disagree, affirm the circuit court's judgment, and confirm the Department's final administrative decision.

¶ 3 I. BACKGROUND

¶ 4 Plaintiff holds both a wholesale drug distributor license in the State of Illinois and a wholesale distributor of dangerous drugs license in the State of Ohio. In January 2017, the Ohio Board of Pharmacy imposed a $4000 penalty on plaintiff for selling wholesale pharmaceuticals between 2007 and 2009 to customers in Ohio without being registered as a wholesale distributor of dangerous drugs. Plaintiff paid the penalty, and its license was in good standing. In November 2017, the Department filed a complaint against plaintiff, alleging it violated section 1510.50(i) of Title 68 of the Illinois Administrative Code (68 Ill. Adm. Code 1510.50(i), adopted at 16 Ill. Reg. 12216 (eff. July 17, 1992)) and sections 26, 55(a)(1), and 55(a)(5) of the Wholesale Drug Distribution Licensing Act (Licensing Act) (225 ILCS 120/26, 55(a)(1), (a)(5) (West 2018)) by failing to comply with regulations in Ohio. The complaint alleged plaintiff's actions were grounds for discipline under section 55(a)(1) and 55(a)(5) of the Licensing Act (225 ILCS 120/55(a)(1), (a)(5) (West 2018)). Plaintiff filed an answer and a motion to dismiss. In its motion to dismiss, plaintiff asserted, *inter alia*, section 55(a)(5) was preempted by federal law.

¶ 5 The Department filed an amended complaint, and plaintiff again filed an answer and a motion to dismiss. The motion to dismiss again asserted federal preemption. The Department filed a response to the motion to dismiss, contending plaintiff's preemption claim was based on the supremacy clause of the United States Constitution (U.S. Const., art. VI, cl. 2) and

administrative agencies lack the authority to invalidate a statute on constitutional grounds or even question the statute's validity. Plaintiff filed a reply, contending section 40 of the Licensing Act (225 ILCS 120/40 (West 2018)) recognizes the preemption of federal law. The administrative law judge issued an order denying plaintiff's motion to dismiss the amended complaint. Regarding preemption, the administrative law judge found plaintiff's argument raises constitutional questions and administrative agencies lack the power to determine constitutional issues.

¶ 6 On March 21, 2018, the administrative law judge held a formal evidentiary hearing. Only documentary evidence was presented at the hearing. In April 2018, the administrative law judge filed its report and recommendation. The administrative law judge found the Department's Board of Pharmacy (Pharmacy Board) had jurisdiction over the subject matter and the parties and the Department proved by clear and convincing evidence plaintiff violated section 55(a)(1) and 55(a)(5). It recommended plaintiff be fined $1500. In May 2018, the Pharmacy Board issued its findings of fact, conclusions of law, and recommendation to the Director, adopting the administrative law judge's findings and recommendation. Plaintiff filed a motion for rehearing, noting the issue of federal preemption was neither addressed in the Pharmacy Board's findings of fact, conclusions of law, and recommendations to the Director nor in the administrative law judge's report and recommendation. On September 17, 2018, the Director entered her order and adopted the Pharmacy Board's findings of fact, conclusions of law, and recommendations and ordered plaintiff to pay a $1500 fine. The Director noted plaintiff's federal preemption argument was improperly raised in these proceedings. She further found the discipline in this case was not duplicative or redundant because "the fact plaintiff was disciplined in Ohio is on its own cause for disciplinary action in Illinois."

¶ 7 On October 22, 2018, plaintiff filed a timely complaint for administrative review

under the Administrative Review Law (735 ILCS 5/art. 3 (West 2018)), as provided by section 160 of the Licensing Act (225 ILCS 120/160 (West 2018)). In its complaint, plaintiff asserted defendants lacked jurisdiction to discipline or fine plaintiff for acts that occurred in a different state. It also contended the September 2018 order was preempted by federal law. Additionally, plaintiff argued the order was contrary to law because (1) the Department's amended complaint did not allege plaintiff was engaging in wholesale distribution of human prescription drugs within Illinois and (2) plaintiff had already been subject to discipline in Ohio and should not be subject to further discipline. In January 2019, defendants filed a notice of special and limited appearance and a motion to dismiss pursuant to section 2-619(a) of the Procedure Code (735 ILCS 5/2-619(a) (West 2018)), asserting the circuit court lacked jurisdiction. In June 2019, the court entered a written order granting defendants' motion and dismissing plaintiff's complaint with prejudice. As stated, plaintiff appealed, and this court reversed the circuit court's dismissal and remanded the cause for further proceedings. *X-Gen Pharmaceuticals, Inc.*, 2020 IL App (4th) 190657-U.

¶ 8 On remand, the parties filed briefs, addressing plaintiff's contentions. The circuit court held oral arguments in March 2021. On April 5, 2021, the court entered a written order, denying the petition for judicial review and affirming the Department's final decision. The court did not find a preemption issue or a constitutional violation.

¶ 9 On June 3, 2021, plaintiff filed a timely motion for leave to file a late notice of appeal with this court pursuant to Illinois Supreme Court Rule 303(d) (eff. July 1, 2017), which this court allowed. On June 14, 2021, plaintiff filed a notice of appeal in sufficient compliance with Illinois Supreme Court Rule 303 (eff. July 1, 2017). Accordingly, this court has jurisdiction of this appeal under Illinois Supreme Court Rule 301 (eff. Feb. 1, 1994).

¶ 10 II. ANALYSIS

¶ 11 Plaintiff asserts the Department's authority to impose reciprocal discipline is preempted by federal law. Defendants disagree.

¶ 12 With administrative cases, this court generally reviews the administrative agency's decision, not the circuit court's. *Outcom, Inc. v. Illinois Department of Transportation*, 233 Ill. 2d 324, 337, 909 N.E.2d 806, 814 (2009). Section 3-110 of the Administrative Review Law (735 ILCS 5/3-110 (West 2018)) allows review of "all questions of law and fact presented by the entire record before the court" but does not allow the reviewing court to consider any new or additional evidence. We recognize federal preemption claims are outside the purview of the administrative agency. See *Poindexter v. State*, 372 Ill. App. 3d 1021, 1026, 869 N.E.2d 139, 144-45 (2006). Regardless of which decision we review, questions of federal preemption and statutory interpretation present questions of law, which this court reviews *de novo*. *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39, 927 N.E.2d 1207, 1214 (2010).

¶ 13 The preemption doctrine derives from the supremacy clause of the United States Constitution and provides "the laws of the United States 'shall be the supreme Law of the Land *** any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.' " *Carter*, 237 Ill. 2d at 39 (quoting U.S. Const., art. VI, cl. 2). As such, if a state law conflicts with federal law, the state law is null and void. *Carter*, 237 Ill. 2d at 39. Federal law preempts state law under one of the following three circumstances:

> "(1) express preemption—where Congress has expressly preempted state action; (2) implied field preemption—where Congress has implemented a comprehensive regulatory scheme in an area, thus removing the entire field from the state realm; or (3) implied conflict preemption—where state action actually conflicts with

federal law." *Carter*, 237 Ill. 2d at 39-40.

In any preemption analysis, the key is to determine Congress's intent. *Carter*, 237 Ill. 2d at 40.

¶ 14 In this case, plaintiff asserts express preemption and cites section 360eee-4 of the Federal Food, Drug, and Cosmetic Act (Drug Act) (21 U.S.C. § 360eee-4 (2018)). With an express preemption clause, any presumption against preemption is not invoked, and the focus is on the clause's plain wording, " 'which necessarily contains the best evidence of Congress' preemptive intent.' " *Puerto Rico v. Franklin California Tax-Free Trust*, 579 U.S. 115, 125 (2016) (quoting *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594 (2011)).

¶ 15 Section 360eee-4(b)(1) of the Drug Act, which was part of the Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (eff. Nov. 27, 2013), contains the preemption clause regarding wholesale distributors and states, in pertinent part, the following:

> "Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor *** licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 353(e) of this title, in the case of a wholesale distributor ***." 21 U.S.C. § 360eee-4(b)(1).

Notwithstanding the aforementioned preemption clause, states may do the following things related to wholesale distributors: (1) "take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 353(e) of this title or this part," (2) "provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State," and (3) "provide for fines, imprisonment, or civil penalties" for a "conviction of violations of Federal, State, or local drug laws or regulations." 21 U.S.C. § 360eee-4(b)(4)(A)-(C).

Additionally, section 360eee-4(c) of the Drug Act provides, in pertinent part, the following: "Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to *** wholesale distributor *** licensure as described in subsection (b) applicable under section 353(e) of this title or this part (or regulations issued thereunder)." 21 U.S.C. § 360eee-4(c). Since the plain language of the preemption clause refers to section 353(e) for the standards and requirements applicable to the licensure of wholesale distributors, we examine the language of that provision.

¶ 16 Section 353(e) of the Drug Act (21 U.S.C. § 353(e) (2018)) is a lengthy provision that addresses, *inter alia*, licensing and reporting requirements for wholesale distributors. The licensing requirement begins by stating it is subject to section 360eee-2 of the Drug Act (21 U.S.C. § 360eee-2 (2018)). 21 U.S.C. § 353(e)(1). It next provides no person may engage in the wholesale distribution of drugs without a license and the license must "meet the standards, terms, and conditions established by the Secretary under section 360eee-2 of this title." 21 U.S.C. § 353(e)(1)(A), (B). The "Secretary" is the Secretary of Health and Human Services. 21 U.S.C. § 321(d) (2018). Section 360eee-2(a) provides, "The Secretary shall, not later than 2 years after November 27, 2013, establish by regulation standards for the licensing of persons under section 353(e)(1) of this title, including the revocation, reissuance, and renewal of such license." 21 U.S.C. § 360eee-2(a). Section 360eee-2(b) then provides that,"[f]or the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 353(e)(1) of this title and shall include standards for the following" and lists seven categories. 21 U.S.C. § 360eee-2(b). Thus, section 353(e) and section 360eee-2 do not contain the licensing standards and requirements referred to in the preemption clause but, rather, delegate the task to the Secretary to establish the

standards and requirements in regulations.

¶ 17 Defendants suggest the preemption clause has yet to become effective because the Secretary has not yet promulgated the regulations required by section 360eee-2(a). See National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers; Extension of Comment Period, 87 Fed. Reg. 31439 (May 24, 2022) (to be codified at 21 C.F.R. pts. 10, 12, 16, 205) (extending the comment period on the proposed rule until September 6, 2022). At the October 25, 2022, oral arguments in this case, neither party was aware of any action taken by the Secretary on the proposed rule. Plaintiff responds the preemption clause, section 353(e), and section 360eee-2 all went into effect on November 27, 2013. It further asserts 21 C.F.R. 205 was effective at the time of the disciplinary action in this case and outlined the minimum standards and requirements for the licensure of wholesale drug distributors. However, the purpose of 21 C.F.R. 205 was to implement the Prescription Drug Marketing Act of 1987 and not the Drug Quality and Security Act that went into effect in 2013. See 21 C.F.R. § 205.2 (1997). Section 360eee-4(b)(1) is part of the Drug Quality and Security Act and references section 353(e), which is subject to section 360eee-2. Since section 360eee-2 requires the Secretary to establish by regulation standards applicable to all State and Federal licenses under section 353(e)(1), and those regulations have yet to be promulgated, the preemption clause is just empty language until those regulations take effect. Thus, we agree with defendants the preemption clause of the Drug Quality and Security Act is not currently in effect. Moreover, even if 21 C.F.R. 205 did contain the standards and requirements referred to in the preemption clause and made the preemption clause effective, plaintiff does not identify any language in those regulations supporting its preemption claim. As such, plaintiff has failed to establish express preemption of reciprocal discipline.

¶ 18 III. CONCLUSION

¶ 19 For the reasons stated, we affirm the Sangamon County circuit court's judgment and confirm the Department's final administrative decision.

¶ 20 Affirmed.

X-Gen Pharmaceuticals, Inc. v. Department of Professional Regulation,
2022 IL App (4th) 210325

Decision Under Review:	Appeal from the Circuit Court of Sangamon County, No. 18-MR-821; the Hon. Christopher G. Perrin, Judge, presiding.
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Attorneys for Appellee:	Kwame Raoul, Attorney General, of Chicago (Jane Elinor Notz, Solicitor General, and Mary C. LaBrec, Assistant Attorney General, of counsel), for appellees.