UNITED STATES DISTRICT COURT EASTERN DISTRICT OF KENTUCKY SOUTHERN DIVISION AT PIKEVILLE

HUMANA INC.,

CIVIL NO. 7:18-CV-64-KKC

Plaintiff,

 \mathbf{v} .

OPINION AND ORDER

CELGENE CORPORATION

Defendant.

*** *** ***

This matter is before the Court on Humana Inc.'s Motion to Remand to the Pike County Circuit Court. (DE 16). For the reasons stated below, the Motion is **GRANTED**.

I. BACKGROUND

Humana Inc. ("Humana") filed its Complaint in state court against Celgene Corporation ("Celgene") asserting six causes of action—(1) fraud, (2) breach of contract, (3) negligent misrepresentation, (4) unjust enrichment, (5) violations of New Jersey's RICO statute ("NJ RICO"), and (6) conspiracy to violate NJ RICO. (DE 1-1 at 29-38.) Humana's claims ultimately stem from insurance benefits it paid on behalf of its insured for two drugs produced by Celgene, Thalomid and Revlimid. (DE 1-1.) Humana's first three claims are premised on a breach of contractual representations and warranties. (DE 1-1 at 29-32.) Humana asserts that Celgene fraudulently or negligently induced it to enter into contracts which required it to provide coverage for Thalomid and Revlimid prescribed for ineffective and unsafe purposes in contravention of local, state, and federal law. (DE 1-1 at 29-32.) Humana further asserts that Celgene was unjustly enriched through its actions. (DE 1-1 at

33.) In its final two claims, Humana asserts that Celgene is liable under New Jersey's RICO Act, N. J. Stat. Ann. § 2C:41-2(c) and (d), because it deliberately misrepresented the uses for which Thalomid and Revlimid have been proven to be effective; provided or caused to be provided written materials to physicians containing false and misleading information on which physicians were intended to rely; and actively concealed information about Celgene's off-label marketing activities. (DE 1-1 at 34-37.)

Celgene removed the case to the Eastern District of Kentucky on the basis of federal question jurisdiction. (DE 1 at 1.) Celgene asserts that this action is replete with federal questions because in order to prevail, Humana must prove violations of the Food Drug and Cosmetics Act ("FDCA") or violations of regulations promulgated by the Food and Drug Administration ("FDA"). (DE 1 at 2-5.) Humana now moves for remand under 28 U.S.C. § 1447(c), asserting that this case was improperly removed because it does not arise under federal law. (DE 16-1 at 1). Accordingly, Humana claims that this Court does not have subject matter jurisdiction.

II. ANALYSIS

Although there are several motions pending in this matter, the Court must first determine whether removal from the Pike County Circuit Court was proper. On a motion to remand, the defendant bears the burden to show that this Court has original jurisdiction. Eastman v. Marine Mech. Corp., 438 F. 3d 544, 549 (6th Cir. 2006). Original jurisdiction exists through either diversity of citizenship, see 28 U.S.C. §§ 1332(a) and 1441(b), or federal question jurisdiction, see 28 U.S.C. §§ 1331 and 1441(a). When there are any doubts as to the propriety of removal, "the removal statute should be strictly construed and all doubts resolved in favor of remand." Eastman, 438 F. 3d at 550. It is uncontested that there is no diversity of citizenship among the parties because Humana and Celgene are both citizens of

Delaware. (DE 1-1 at 6-8.) The Court considers the parties' arguments on federal question jurisdiction below.

A. Federal question jurisdiction.

Courts have consistently applied the well-pleaded complaint rule when reviewing federal question jurisdiction on a motion to remand. "To determine whether the claim arises under federal law, we examine the 'well pleaded' allegations of the complaint and ignore potential defenses." *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 560 (6th Cir. 2007) (quoting *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 6 (2003)). As a result of the rule, "federal questions presented by defenses—or even by the plaintiff's anticipatory rebuttal of an expected defense—cannot support jurisdiction." *Dillon v. Medtronic, Inc.*, 992 F.Supp.2d 751, 755 (2014) (citing *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 10 (1983)).

In its Complaint, Humana does not rely on a federal cause of action. Instead, it asserts several state-law causes of action against the defendant. (DE 1-1 at 29-38.) Consequently, the claims within the well-pleaded complaint do not directly arise under federal law or jurisdiction.

However, the United States Court of Appeals for the Sixth Circuit recognizes three exceptions to the well-pleaded complaint rule, by which the defendants could still show that federal jurisdiction is proper. *See Mikulski*, 501 F.3d at 560. The first two exceptions, artfulpleading and complete preemption, are not applicable to this case. Only the third exception, the substantial federal question doctrine, is at issue.

1. The substantial federal question doctrine.

Celgene relies on the substantial federal question doctrine in removing this case to federal court. (DE 1.) The United States Supreme Court has held that federal courts have federal question jurisdiction over state-law claims that raise a substantial federal issue, but only

when the exercise of such jurisdiction will not upset the balance of state and federal judicial responsibilities. See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 314 (2005).

The substantial federal question doctrine only applies to a "special and small category of cases." Gunn v. Minton, 568 U.S. 251, 258 (2013). The Sixth Circuit, relying on Grable, has adopted a three-part test to determine whether state-law claims implicate federal question jurisdiction—(1) The state-law claim must necessarily raise a disputed federal issue; (2) the federal interest in issue must be substantial; and (3) the exercise of jurisdiction must not disturb any congressionally approved balance of federal and state judicial responsibilities. Mikulski, 501 F.3d at 568. For federal jurisdiction to lie under the substantial federal question doctrine, the removing defendant must show that all factors are fulfilled. See id.

Celgene asserts that Humana's claims for fraud, breach of contract, violations of NJ RICO, and conspiracy to violate NJ RICO all raise substantial federal questions which give this Court subject matter jurisdiction. (DE 1.) Celgene concedes that Humana's claims for negligent misrepresentation and unjust enrichment raise no federal issues. (See DE 45 at 8.) Accordingly, this Court will consider only whether Humana's remaining claims raise substantial federal questions. For the reasons stated below, the Court does not have subject matter jurisdiction over the claims in this case.

a. Whether Humana's state-law claims necessarily raise a disputed federal issue.

A federal issue is necessarily raised where a state-law claim depends on the adjudication of a federal issue. *Gunn*, 568 U.S. at 258. However, "when a claim can be supported by alternative and independent theories—one of which is a state-law theory and one of which is a federal law theory—federal question jurisdiction does not attach because federal law is not

a necessary element of the claim." Rains v. Criterion Sys., Inc., 80 F.3d 339, 346 (9th Cir. 1996); See also Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809-10 (1988).

Celgene asserts that Humana's claims for fraud, breach of contract, violations of NJ RICO, and conspiracy to violate NJ RICO are necessarily raised under federal law. Celgene argues that federal law is an essential element of Humana's claims because "Humana can prevail on four of its six causes of action *only* if it establishes that Celgene violated the federal law governing off-label promotion." (DE 45 at 8.)

i. Humana's fraud and breach of contract claims.

It is not this Court's job to determine whether Humana will prevail on its claims, but instead to determine whether there is federal jurisdiction to adjudicate the claims. It is unclear whether a disputed federal issue is raised in Humana's fraud and breach of contract claims. Although Humana makes significant reference to FDA laws and regulations, its claims for relief reference federal, state, and local laws. (DE 1-1.) Additionally, Humana chose to bring its claims specifically under Kentucky tort and contract law. (DE 1-1 at 29-32.) Humana asserts that it can support its claims on an exclusively state-law theory by showing that Thalomid and Revlimid were unsafe, ineffective, and fraudulently promoted. (DE 16-1 at 9.) However, Humana's specific claims for relief only cite FDA laws and regulations. (DE 1-1 at 29-32.) While the Court recognizes that Humana has asserted that Thalomid and Revlimid were promoted for uses that were unsafe and ineffective, the Court struggles to see how this theory is wholly "independent" from its federal theory asserting liability stemming from violations of FDA laws and regulations. See Rains, 80 F.3d at 346; Christianson, 486 U.S. at 809-10.

Under Kentucky tort law, a party claiming fraud must establish six elements by clear and convincing evidence—(1) a material representation, (2) which is false, (3) known to be false or made recklessly, (4) made with inducement to be acted upon; (5) acted in reliance thereon;

and (6) causing injury. Brown v. Louisville Jefferson Cty. Redevelopment Auth., Inc., 310 S.W.3d 221 (Ky. Ct. App. 2010). Under Kentucky contract law, to establish a breach of contract, the complainant must establish (1) the existence of contract; (2) breach of that contract; and (3) damages flowing from the breach of contract. Metro Louisville/Jefferson Cty. Gov't v. Abma, 326 S.W.3d 1, 8 (Ky. Ct. App. 2009).

Humana's Complaint provides nearly thirty pages of factual information and allegations giving rise to its claims for relief. (DE 1-1 at 1-29.) Humana alleges violations of FDA laws and regulations as part of an overall scheme whereby Celgene promoted Thalomid and Revlimid for off-label uses and actively concealed information regarding safety and efficacy of the drugs. (DE 1-1 at ¶¶ 13, 14, 17, 88, 99, and 140.) While Humana does not fully restate this scheme in the section of its Complaint listing the claims of relief for fraud and breach of contract, it incorporates the scheme and other factual information giving rise thereto by reference. (DE 1-1 at ¶¶ 108, 117, 124, 129, 133, and 147.)

Humana's Complaint emphasizes that its fraud claim is premised on representations made in contracts between Celgene and Humana. (DE 1-1 at 29-32.) In these contracts, Celgene was required to ensure that the products subject to the agreement, including Thalomid and Revlimid, "comply with all applicable laws, regulations, directives, and requirements of the FDA, including without limitation, packaging and labeling requirements, product warning requirements, product design, and safety requirements, and advertising requirements." (DE 1-1 at 29.) Further, such contracts provided that "Celgene represents and warrants that it shall comply with all other applicable federal, state, and local laws, regulations and ordinances related to its business." (DE 1-1 at 29.) Humana does not argue that Celgene is liable for fraud because it promoted drugs for off-label uses. Instead, it alleges an overall scheme to conceal information affecting the safety and efficacy of the off-label uses of Thalomid and Revlimid in violation of federal law.

It is unclear whether a disputed federal issue is necessarily raised in this context. Violations of federal law are not an explicit element of Humana's state-law fraud and breach of contract claims. However, in order to show that Celgene made fraudulent contractual representations, Humana would be required to reference Celgene's duties and obligations under the FDA.

Celgene further argues that it "vigorously" disputes the effect of the FDA laws and regulations at issue. (DE 45 at 12.) To support its argument, Celgene poses a series of hypothetical questions which it purports will arise as this case progresses. Celgene states:

Humana and Celgene clearly disagree about the contours of federal law in this area... For instance: Can a plaintiff, consistent with the First Amendment, impose liability on a manufacturer for engaging in truthful and nonmisleading communications about off-label uses of its pharmaceuticals? Are all off-label discussions forbidden, or only those involving representations as to a pharmaceutical's safety and efficacy? Where is the line between unlawful promotional efforts and lawful discussions between a manufacturer's representative and a physician? These are all core questions about the meaning of federal law that are certain to feature prominently in this litigation (if Humana's claims ever get off the ground). (DE 45 at 13.)

Celgene's First Amendment argument cannot grant federal jurisdiction. A defendant cannot remove a case to federal court unless the plaintiff's complaint establishes that the claims arise under federal law. See Dillon, 992 F.Supp.2d at 755. A defendant is prohibited from removing a case based on a statutory or constitutional defense, even if the defense is anticipated by both parties. Id. Assuming that there is a First Amendment issue, the issue is raised by Celgene as a defense to Humana's state-law claims. This is not sufficient to confer jurisdiction.

For federal jurisdiction to lie, there must be a dispute over the validity, construction, or effect of federal law. *See Mikulski*, 501 F.3d at 565. Humana does not contest the validity, construction, or effect of FDA laws or regulations. Moreover, Celgene fails to identify a single conflicting interpretation regarding the effect of any FDA law or regulation. (*See* DE 45 at

12-15.) Notably, Humana and Celgene agree on the content of the relevant federal laws and regulations governing off-label marketing of pharmaceuticals. (See DE 1-1 at 8-10; DE 1 at 2.) They agree that the FDA laws and regulations provide mechanisms by which a pharmaceutical company can speak to a drug's off-label uses. (See DE 1-1 at 8-10; DE 1 at 2; DE 48 at 6.) Their only disagreement seems to be whether Celgene's conduct amounted to a violation of such laws and regulations. (DE 16-1 at 12; DE 45 at 7). But even assuming there are disputed federal issues, the issues are not substantial.

ii. Humana's NJ RICO and conspiracy to violate NJ RICO claims.

Humana can support its claims for violations of NJ RICO and conspiracy to violate NJ RICO on a state-law theory. Humana alleges a violation under N. J. Stat. Ann. 2C:41-2(c), which requires a plaintiff to prove (1) the existence of an enterprise affecting trade or commerce; (2) that the defendant was employed by or associated with the enterprise; (3) that the defendant participated either directly or indirectly, in the conduct or the affairs of the enterprise; and (4) that the defendant participated through a pattern of racketeering activity that must include the allegation of at least two predicate acts. *Horowitz v. Marlton Oncology, P.C.*, 116 F.Supp. 551, 553-54 (D. N. J. 1999). Humana also alleges a violation under N. J. Stat. Ann. 2C:41(d), which, in addition to the above, requires Humana to show the existence of a conspiracy. *See* N. J. Stat. Ann. § 2C:5-2.

Humana's Complaint alleges an overall scheme by which Celgene deliberately misrepresented the uses for which Thalomid and Revlimid have been proven to be effective; provided or caused to be provided written materials to physicians containing false and misleading information on which physicians were intended to rely; and actively concealed information about Celgene's off-label marketing activities. (DE 1-1 at ¶ 140.) Humana asserts predicate acts that are also violations of federal law—the mail- and wire-fraud statues and the Travel Act. (DE 1-1 at ¶ 139). Celgene asserts that because the NJ RICO statute

imports federal definitions of racketeering activity and Humana asserts those predicate acts that violate federal law, then its causes of action for violations of NJ RICO and conspiracy to violate NJ RICO arise under federal law. (DE 45 at 12.) Celgene states that "Humana must prove that Celgene both actually engaged in federally prohibited off-label promotion...and also that this conduct violated the federal statutes Humana identifies (as Celgene's predicate acts)." We disagree.

Here, New Jersey borrowed a federal definition for an element of its state-law RICO statute. "That New Jersey borrowed a federal definition for an element of this state-law cause of action cannot operate to confer jurisdiction upon the federal court." *Horowitz*, 116 F. Supp. 2d at 556. Celgene does not necessarily disagree, but instead asserts that this case involves "a second layer of federal law" that was absent in *Horowitz*. (DE 45 at 12.) To support its argument, Celgene relies on an Eleventh Circuit case, *Ayres v. Gen. Motors Corp.*, 234 F.3d 514 (11th Cir. 2000). (DE 45 at 11-12.) *Ayers* involved a specific question of federal law—whether the National Traffic and Motor Vehicle Safety Act ("Safety Act") created a duty to disclose which would amount to a violation of federal mail and wire fraud statutes. *Id.* at 518-21. The Court, assuming that such a duty was created under the Safety Act, had to examine the Safety Act to determine whether a breach of the duty was intended to confer criminal or civil liability. *Id.*

Such an examination of FDA laws and regulations is not required here. Humana's claims for violations of NJ RICO and conspiracy to violate NJ RICO do not require Humana to show specific violations of FDA laws and regulations. Humana asserts that Celgene was involved in a scheme whereby it deliberately misrepresented the uses for which Thalomid and Revlimid have been proven to be effective; provided or cause to be provided written materials to physicians containing false and misleading information on which physicians were intended to rely; and actively concealed information about Celgene's off-label marketing activities.

(DE 1-1 at ¶ 140.) These allegations are enough to support the elements of N. J. Stat. Ann. 2C:41-2(c) and (d) without reference to FDA laws and regulations. For example, Humana could show racketeering activity by showing violations of the wire-fraud statue. Consistent with the wire-fraud statute, Humana could show that Celgene devised a scheme to defraud consumers by providing false information to physicians regarding Thalomid and Revlimid. See 18 U.S.C.A. § 1343. Humana could then show that Celgene transmitted such information by wire. Id. None of this would require examination of FDA laws and regulations. But again, even assuming there are disputed federal issues, the issues are not substantial.

b. Whether the federal issues are substantial.

The Sixth Circuit has set forth four factors for determining whether a state-law claim implicates substantial federal issues:

(1) Whether the case includes a federal agency, and particularly, whether that agency's compliance with the federal statute is in dispute; (2) whether the federal question is important (i.e., not trivial); (3) whether a decision on the federal question will resolve the case (i.e. the federal question is not merely incidental to the outcome); and (4) whether a decision as to the federal question will control numerous other cases.

Mikulski, 501 F.3d at 570.

These factors should be considered collectively along with any other factors that may be applicable. *Id.* No single factor is dispositive. *Id.*

First, no claims in this case implicate any federal agency or call upon this Court to review an agency's compliance with the federal statute in dispute. *See Mikulski*, 501 F.3d at 568-570. Instead, the case deals with the conduct of a private company—Celgene—which allegedly violated state contract, tort, and RICO laws.

Celgene asserts that the "FDA's regulatory regime looms large" and that the "federal government routinely litigates off-label claims under this regulatory scheme." (DE 45 at 16.) But this is not surprising considering that the FDA provides no private right of action. See 21 U.S.C. § 337(a). Moreover, while the federal government may have an interest in the

uniform application of FDA laws and regulations, it only has a limited interest in private tort or contract litigation involving such laws and regulations. See, e.g., Mikulski, 501 F.3d at 570 ("While the federal government may have an interest in the uniform application of regulations that relate to the collection of taxes, it has only a limited interest in private tort or contract litigation over the private duties involved in that collection.") Lee v. Kirkpatrick, No. 1:16-CV-00123-GNS, 2016 WL 7197478, at *4 (W.D. Ky. Dec. 9, 2016) ("While the government undoubtedly has an interest in regulating the dispensation of controlled substances by healthcare providers, it has only a limited interest in litigation over private, state-law tort duties that happen to involve the administration of controlled substances."); Boggs v. Merideth, No. 3:16-cv-00006-TBR, 2017 WL 1088093, at *5 (W.D. Ky. 2017) ("[A]lthough the FAA certainly has an interest in enforcing its regulations governing federal airspace, its interest in applying those regulations in the context of a state-law tort claim for trespass to chattels is limited or nonexistent.").

Second, the federal questions that may be raised in this litigation are not important. This inquiry considers whether the issues are significant to the federal system as a whole. *Gunn v. Minton*, 568 U.S. 251, 263 (2013). Here, Celgene asserts that "Humana seeks to hold [it] liable for allegedly engaging in truthful and non-misleading discussions regarding off-label uses[.]" (DE 45 at 17). But Humana would agree that truthful and non-misleading discussions regarding off-label uses—in compliance with the FDA—do not generate liability. (*See* DE 1-1 at 9-10.) If anything, Humana is asserting that Celgene was untruthful in spreading misleading information regarding the safety and efficacy of Thalomid and Revlimid. It also alleges, and thoroughly describes, a scheme by which Celgene circumvented FDA laws and regulations under a guise resembling compliance. (DE 1-1 at 10-28.) This is not a case involving any meaningful interpretation or effect of FDA laws and regulations, but

whether Celgene acted in contravention of those laws and regulations. This question is unique to this case and is not important to the federal system as a whole.

Celgene cites concern that state courts will develop an "inconsistent body of law" for cases involving violations of FDA laws and regulations. (DE 45 18.) However, its concerns are unfounded. State courts are presumed competent to interpret and apply federal law. Zwickler v. Koota, 389 U.S. 241, 245 (1967). Moreover, state courts "can be expected to hew closely to the pertinent federal precedents." Gunn, 568 U.S. at 262. Celgene even signals that federal courts have already developed an expansive body of law concerning off-label promotion and marketing. (See DE 45 at 22.) Accordingly, Celgene has failed to show that the issues involved in this litigation are so important that they fall within the "special and small category of cases" granting federal jurisdiction. See Gunn, 568 U.S. at 258.

Third, a decision on the federal question will not resolve the case because Humana will still need to prove each element of every claim to prevail. Ultimately, any violation of FDA laws or regulations will only be used as evidence to support a broader violation of state-law.

Finally, a decision as to whether Celgene's conduct amounted to violations of FDA laws and regulations will not control numerous cases in the future. Courts have already developed a body of law interpreting the provisions of FDA laws and regulations governing off-label promotion. See, e.g., In re Actimmune Mktg. Litig., 614 F. Supp. 2d 1037, 1051 (N.D. Cal. 2009); In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig., No. 3:09-CV-20071-DRH, 2010 WL 3119499, at *1 (S.D. Ill. Aug. 5, 2010); Blain v. Smithkline Beecham Corp., 240 F.R.D. 179, 186 (E.D. Pa. 2007); United States v. Lanpar Co., 293 F. Supp. 147, 154 (N.D. Tex. 1968). There is nothing to suggest that this case involves any novel interpretation or application of FDA laws and regulations. Instead, it will likely involve a routine application of well-settled laws and regulations to the unique conduct of Celgene in

its promotion of Thalomid and Revlimid. The Court fails to see how such application would be controlling in numerous future cases.

All four factors indicate that the federal issues present in this litigation are insubstantial. Further, Celgene has not proposed any additional factors for this Court to consider in its substantiality analysis. Because the federal issues present in this case are not substantial, the Court does not have subject matter jurisdiction.

c. Whether the exercise of jurisdiction will disturb any congressionally approved balance of federal and state judicial responsibility.

In analyzing this factor, the Court must consider whether Congress has created a private right of action under the federal law at issue. See Grable, 545 U.S. at 318-319 (citing Merrell Dow Pharmaceuticals Inc., v. Thompson, 478 U.S. 804, 106 S.Ct. 3229 (1986)). Congress has not provided a private right of action under the FDA and has not explicitly preempted such claims from being brought in state court. 21 U.S.C. § 337(a); Mikulski, 501 F.3d at 563-564. While not dispositive, "the absence of a private right of action suggests that Congress did not intend for federal courts to exercise jurisdiction." PremierTox, Inc. v. Kentucky Spirit Health Plan, Inc., No. 1:12CV-00010-JHM, 2012 WL 1950424, at *7 (W.D. Ky. May 30, 2012). Congress's choice is "an important clue to [its] conception of the scope of jurisdiction to be exercised under § 1331." Grable, 545 U.S. at 318.

Congress's failure to include a private right of action under the FDA and decision not to preempt such claims suggests that Congress did not intend for federal courts to exercise jurisdiction over the traditionally state-law claims alleged by Humana. *Id.* at 318-19. ("Merrell Dow thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome any state-law tort case implicating federal law 'solely because the violation of the federal statute is said to [create] a rebuttable presumption [of negligence] ... under state law.") (quoting *Merrell Dow*, 478 U.S. at 811-12).

Accordingly, the Court finds that exercising jurisdiction over Humana's claims would disturb the congressionally approved balance between federal and state courts.

III. CONCLUSION

After having considered all relevant factors, this Court concludes that Humana's claims do not raise substantial federal issues. Celgene has not carried its burden in showing that this Court has federal question jurisdiction. See Eastman, 438 F. 3d at 549; 28 U.S.C. §§ 1331. The insubstantiality of the federal issues at play combined with the disruption of the balance between federal and state courts cause this Court to conclude that it does not have subject matter jurisdiction over Humana's claims. Accordingly, pursuant to 28 U.S.C. § 1447(c), the matter shall be remanded to the Pike Circuit Court for further consideration.

Based on the foregoing, the Court **HEREBY ORDERS** as follows:

- (1) Humana's Motion to Remand (DE 16) is **GRANTED**. This matter is **REMANDED** to the docket of the Pike County Circuit Court.
- (2) All remaining motions (DE 11 and 12) are **DENIED AS MOOT**.
- (3) This case is **STRICKEN** from the Court's active docket.

Dated March 29, 2019.

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KAREN K. CALDWELL, CHIEF JUDGE UNITED STATES DISTRICT COURT EASTERN DISTRICT OF KENTUCKY

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