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Commentary

Levine To Mensing — A Journey From The Sublime To The Ridiculous

By
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[Editor's Note: Bijan Esfandiari is the lead law and motion attorney at Baum, Hedlund, Aristei & Goldman in Los Angeles and is a member of the firm's pharmaceutical drug product liability litigation team. He has successfully represented clients in state and federal courts across the nation at both the trial and appellate level. He has been at the forefront of the preemption battle and has successfully argued against preemption in numerous published decisions. He successfully briefed and argued the first and only prescription drug preemption case to be heard by the U.S. Seventh Circuit Court of Appeals, Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010), and co-authored Supreme Court amicus briefs in support of the respondents (plaintiffs) in both Levine and Mensing. Copyright © 2011 by Bijan Esfandiari. Responses are welcome.]

Describing the disastrous consequences of his failed Russian invasion, Napoleon lamented “There is but one step from the sublime to the ridiculous.”¹ Such is the case here. Just two years ago, the Supreme Court held that failure to warn claims against *name-brand* drug manufacturers are not preempted by federal law, see *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), however, the same court has now held that failure to warn claims against *generic* drug manufacturers are preempted. *Pliva v. Mensing*, 131 S.Ct. 2567 (2011). In this article, we explore the steps the Supreme Court took from its sublime ruling in *Levine* to the ridiculous one in *Mensing*.

A. The Genesis Of The Preemption Doctrine And Its Application To Prescription Drugs

The doctrine of preemption is rooted in the Supremacy Clause of the Constitution, which provides that “the Laws of the United States . . . shall be the supreme Law

of the Land.”² In the seminal case *Gibbons v. Ogden*, the Supreme Court interpreted this language to invalidate state laws that “interfere with, or are contrary to,” federal law, the genesis of the preemption doctrine. One situation in which preemption arises is when state law “conflicts” with federal law.³ Conflict preemption applies when (a) “compliance with both federal and state regulations is a physical impossibility,” or (b) when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁴

Levine (involving a name brand manufacturer) and *Mensing* (involving generic manufacturers) concerned injured patients who claimed the drug manufacturers failed to provide adequate warnings regarding the risks associated with their respective drugs — the patients sued the manufacturers under various state law theories of liability. In both cases, the drug manufacturers argued that the failure to warn claims were preempted because they could not unilaterally issue enhanced warnings without Food and Drug Administration (FDA) approval and, if they did issue enhanced warnings, they would violate federal law (FDA regulations). Thus, they argued, it was impossible for them to comply with both state law/jury verdicts (which required enhanced warnings) and federal law (which they claimed prohibited the issuance of enhanced warnings). The issue in both cases, therefore, turned on whether the manufacturers were free to issue enhanced warnings under federal law (FDA regulations).

B. The Pharmaceutical Industry ‘Captures’ The FDA

At first blush, it might seem a bit odd that federal statutes and regulations drafted to make drugs safer

would be used by drug manufacturers as a shield against liability. After all, Congress' primary motivation for enacting the Food Drug and Cosmetic Act (FDCA) and creating the FDA was to protect the health and safety of the public.⁵ However, history has taught us that an administrative agency set up to protect the public from certain industries can be "captured" by those industries and turned against the public. This has been referred to as "regulatory capture," a phenomenon discussed and analyzed by numerous commentators, including Nobel Prize winning economists George J. Stigler and Milton Friedman.⁶

As way of example, the Interstate Commerce Act of 1887 created the Interstate Commerce Commission ("ICC") whose initial purpose was to control railroads and their unfair business practices. However, the ICC was soon staffed with employees and lawyers who used to represent the railroad industry. In 1893, Richard Olney, a prominent business lawyer, came to Washington to serve as President Cleveland's Attorney General. Once appointed, Olney's former clients, the railroad tycoons, asked him if he would help eliminate the hated ICC. Olney replied:

The Commission . . . is, or can be made, of great use to the railroads . . . the older such a commission gets to be, the more inclined it will be found to take the business and railroad view of things. It thus becomes a sort of barrier between the railroad corporations and the people and a sort of protection against hasty and crude legislation hostile to railroad interests The part of wisdom is not to destroy the Commission, but to utilize it.⁷

Much the same way the railroad tycoons were able to infiltrate and use the ICC to their advantage, drug manufacturers were able to infiltrate the FDA and utilize it to their advantage. During President George W. Bush's administration, Daniel Troy, Esq., an attorney for the pharmaceutical industry, was appointed as Chief Counsel of the FDA. Once appointed, Mr. Troy and his cronies began to advance the industry's preemption defense by, *inter alia*, drafting FDA *amicus* briefs supporting the drug manufacturer's preemption arguments and revising key regulations and drafting preambles to regulations to further promote preemption.⁸ The industry's capture of the FDA ignited the modern

preemption war, eventually culminating in the *Levine* and *Mensing* rulings.

C. Federal Regulations Applicable To Name-Brand And Generic Manufacturers

Prior to discussing the merits of *Levine* and *Mensing*, a brief background of the regulations that impact drug manufacturers is necessary. All prescription drugs marketed in this country must first be approved by the FDA. To obtain permission to market a brand new product, a drug company (brand name manufacturer) must first submit a New Drug Application (NDA) for the FDA's review and approval.⁹ An NDA must include information about the clinical trials that demonstrate the safety and effectiveness of the product, proposed labeling, and other information.¹⁰ FDA approval includes approval of the labeling, which must identify, *inter alia*, contraindications, warnings, precautions, and adverse reactions.¹¹

Once the brand-name drug loses patent protection, other drug companies may seek permission to market a generic version of an NDA-approved drug.¹² In 1984, Congress adopted the Drug Price Competition and Patent Term Restoration Act, known also as the Hatch-Waxman Act. Pursuant to this bill, the FDA implemented an Abbreviated New Drug Application procedure (ANDA) for manufacturers who produce a generic of a reference-listed drug that has already completed the NDA process.¹³ Generic drugs that go through the ANDA process must (1) be "the same as" a name-brand drug that was already approved by the FDA with respect to active ingredients, route of administration, dosage form, strength and conditions of use recommended in the labeling; or (2) include changes from a name-brand drug if the FDA has approved a petition from a prospective applicant permitting the submission of an ANDA for the changed drug product.¹⁴ One of the benefits to manufacturers who opt for the ANDA procedure is that they are required only to conduct "bioequivalency" studies that establish that the generic and the name-brand drug are pharmaceutically equivalent; the ANDA procedure does not require the safety and effectiveness tests that are necessary under the NDA procedure. In the ANDA, the labeling proposed for the generic product must be the same as the labeling approved for the name-brand drug in all relevant respects.¹⁵

Once the ANDA is approved, generic manufacturers become subject to most of the same statutory and regulatory responsibilities as name brand manufacturers. Notably, both name brand and generic manufacturers have an on-going duty to record and report adverse events to the FDA,¹⁶ and both have a duty to submit annual reports to the FDA discussing various issues, including updated warnings and labeling regarding their drugs.¹⁷ Importantly, under the applicable regulations, *all* drug manufacturers have an obligation to revise their labels “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”¹⁸

To ensure patients are *immediately* warned regarding side effects, FDA regulations permit a manufacturer to utilize the Changes Being Effected (CBE) procedure to “add or strengthen a contraindication, warning, precaution, or adverse reaction” for its drug at any time, without the agency’s prior approval.¹⁹ While the CBE procedure is located in a section of the regulations that is only applicable to name-brand manufacturers, a separate regulation specifically provides that the CBE procedure is equally available and applicable to generic manufacturers.²⁰

D. In *Levine*, The Supreme Court Finds Claims Against Name-Brand Manufacturers Are Not Preempted

In *Levine*, the plaintiff (Diana Levine) was severely injured when a clinician improperly injected an anti-nausea drug Phenergan into her artery. Levine sued Wyeth, the manufacturer of the drug, claiming Wyeth failed to provide an adequate warning regarding the risks involved with the various administering methods of the drug. The case was presented to a jury and the jury concluded that Wyeth failed to properly warn. The issue before the Supreme Court was whether Levine’s claims were preempted by the FDCA and applicable FDA regulations. Wyeth (and the FDA, which filed an *amicus* brief in support of preemption) argued it would have been impossible for Wyeth to comply with both state-law duty and federal law. The Supreme Court rejected Wyeth’s arguments.

The Court rejected Wyeth’s and the FDA’s broad claims of conflict preemption, including claims that, when the FDA approves a drug label, the agency strikes a balance that establishes both a “floor” and a “ceiling”

with respect to the appropriate warnings for that drug. The Court concluded that a drug manufacturer’s claim of implied conflict preemption will fail where it cannot present “clear evidence” that the FDA “would have prohibited” the manufacturer from adding a stronger warning.²¹

In reaching these conclusions, the Court began its analysis with two cornerstones of preemption jurisprudence: the “purpose of Congress” and the “presumption against preemption.” The Court analyzed the legislative history and found that “Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.”²² Further, in light of the historic presence of state law remedies for injured consumers, the Court found that the presumption against preemption applies to implied conflict preemption cases involving prescription drugs.²³

The Court then applied those cornerstone principles to reject Wyeth’s arguments. *First*, the Court rejected Wyeth’s claim that FDA rules gave it no right to change its drug label without prior FDA approval, making it impossible to comply with the jury verdict. The Court found that the FDA’s regulations permit precisely such manufacturer-initiated changes.²⁴

Second, the Court rejected Wyeth’s claim that modifying its label without FDA approval would have rendered its drug misbranded under federal law. The Court explained that the impossibility and misbranding arguments were premised on a “fundamental misunderstanding” of federal drug regulation — that “the FDA, rather than the manufacturer, bears primary responsibility for drug labeling.”²⁵ The Court emphasized that “it has remained a central premise of federal drug regulation that *the manufacturer* bears responsibility for the content of its label at all times” and the manufacturer “is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.”²⁶

Third, the Court rejected the FDA’s position as outlined in its 2006 Preamble and *amicus* briefs, that state-law failure-to-warn claims are preempted because federal approval of a label “establishes both a floor and a ceiling for drug regulation.”²⁷ As the Court explained, the “most glaring problem with this argument is that all evidence of Congress’ purposes is to the contrary.”²⁸ Notably, the Court held

that failure-to-warn lawsuits (a) complement the goals of Congress since such lawsuits “uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly”; (b) “may motivate injured persons to come forward with information”; and (c) “lend force to the FDCA’s premise that manufacturer’s, not the FDA, bear the primary responsibility for the drug labeling at all times.”²⁹ Applying those standards to the facts in *Levine* and finding the record contained no evidence that the FDA would have prohibited Wyeth from strengthening its warning based on the risk information revealed at trial, the Court rejected Wyeth’s preemption arguments.³⁰

The *Levine* decision was celebrated by the public as it ensured that patients injured by prescription drugs would continue to have recourse against negligent and reckless pharmaceutical manufacturers. The decision further ensured that negligent and reckless manufacturers could be held accountable for their negligence and the potential risk of liability would motivate them to adequately warn the public regarding risks associated with their drugs.

Following *Levine*, trial and appellate courts across the country began to reject the preemption defense and numerous preemption rulings were reversed on appeal. Although *Levine* did not involve generic drugs, every appellate court that addressed this issue following *Levine* found (without dissent) that *Levine*’s no-preemption reasoning applied equally to generic drugs.³¹ Given the unanimous and consistent holdings of the Courts of Appeal on this issue, it came as a surprise that the Supreme Court decided to accept review of two generic drug preemption cases.

E. In *Mensing*, The Supreme Court Finds Claims Against Generic-Brand Manufacturers Are Preempted

The Supreme Court accepted review of the Fifth Circuit’s (*Demahy*) and Eighth Circuit’s (*Mensing*) rulings which had found that failure to warn claims brought by injured patients who had used generic Reglan (metoclopramide) were not preempted.³² Metoclopramide is a drug prescribed to treat digestive tract problems such as gastroesophageal reflux disorder. Evidence available to the pharmaceutical manufacturers revealed that long term use of metoclopramide can cause tardive dyskinesia, a severe neurological disorder. The plaintiffs were

both prescribed Reglan by their physicians, however, as is customary, they received generic versions of the drug from their pharmacists. Both plaintiffs developed tardive dyskinesia after taking metoclopramide for several years. Both plaintiffs sued and claimed the generic drug manufacturers were liable under state law³³ for failing to provide adequate warnings regarding the tardive dyskinesia risks associated with prolonged use of metoclopramide. The generic manufacturers argued that FDA regulations prohibited generic manufacturers from unilaterally issuing enhanced warnings and they thus argued that plaintiffs’ claims were preempted.

Plaintiffs argued in the Supreme Court as they had successfully done in the Court of Appeals that, under the FDA regulations, the generic manufacturers had numerous avenues available to them to issue enhanced warnings, including: (a) changing their label pursuant to the CBE procedure just like the name-brand manufacturers; (b) issuing “Dear Doctor” letters to the medical community; and (c) proposing new warnings to the FDA. Plaintiffs therefore argued that it was not impossible for the generic manufacturers to comply with both state and federal law to issue revised warnings.

Without much thought or discussion, the Supreme Court rejected the first two avenues. Relying upon the FDA’s *amicus* brief, the Court held that generic manufacturers were prohibited from unilaterally revising their labels or issuing “Dear Doctor” letters.³⁴ As to the third avenue of asking the FDA to issue revised warnings (which was actually endorsed by the FDA), the Court held that simply asking the FDA to issue a revised warning would not have brought the generic manufacturers in compliance with their state law duties (which required issuance of warnings), and further held that allowing plaintiffs to avoid preemption under the guise of what the FDA *might* have done in response to a labeling request would make the preemption defense “meaningless.”³⁵

There are a number of problems with the Court’s reasoning. *First*, as to the issue of the CBE process, the FDA Regulation, 21 C.F.R. §314.97, specifically provides that the CBE procedure applies to generic manufacturers. The Court’s decision contains no discussion of Section 314.97 and no discussion as to why it should not apply to the *Mensing* case. Rather, the Court (including the dissent) simply adopted the FDA’s interpretation. As previous Supreme Court cases have made

clear, however, it was not necessary for the Court to resort to the FDA's interpretation when there was nothing ambiguous about the statute or regulations in question.³⁶ *Second*, as to the issue of revising the label and/or sending Dear Doctor letters, generic manufacturers have a First Amendment right to issue such warnings/letters. Just last year, in its pro-business *Citizen's United* decision, the Court held that "The First Amendment stands against attempts to disfavor certain subjects or viewpoints. Prohibited, too, are restrictions distinguishing among different speakers, allowing speech by some but not others."³⁷ Yet, in its *Mensing* decision, the Court made the exact type of speech restriction it outlawed in *Citizen's United* — specifically, in *Mensing*, the Court held that name-brand manufacturers are free to unilaterally issue enhanced warnings but that generic manufacturers do not have the same First Amendment rights to engage in such truthful speech. The Court's speaker-based restriction violates the First Amendment.³⁸

Third and finally, the fact the generic manufacturers were permitted to ask the FDA to issue revised warnings should have (as cogently argued by the dissent) been sufficient to overcome the preemption defense.³⁹ The majority held, in part, that, since there was no evidence concerning what the FDA might have done in response to the labeling change request, it cannot suffice to overcome the preemption defense.⁴⁰ However, the majority apparently forgot that the preemption defense is just that — a "defense" — and *defendants* have the burden of establishing this defense by clear evidence.⁴¹ It has long been held that preemption cannot be established by hypothetical conflicts⁴² — yet, that is exactly what the majority permitted the generic manufacturers to do when it accepted their hypothetical preemption arguments.

The FDCA was enacted to encourage and motivate pharmaceutical manufacturers to produce safe and effective drugs and to issue appropriate warnings regarding risks associated with their drugs, however, in direct conflict with the letter and spirit of the FDCA, the Supreme Court's *Mensing* decision incentivizes manufacturers who sit idly by and fail to alert the FDA or the public about the serious risks associated with their drugs.

F. Putting A Price Tag On Admission

Ironically, the majority concedes that its preemption decision "makes little sense" given that just two years

earlier it found similar claims against a name brand manufacturer not preempted.⁴³ The majority admitted that, had the plaintiffs taken the more expensive name-brand drug as opposed the generic drug, then their claims would not have been preempted and "acknowledge[d] the unfortunate hand that federal drug regulations has dealt [plaintiffs] and other similarly situated."⁴⁴ The problem, however, is that the "others similarly situated" includes nearly 75% of all prescription drug users. Most patients, as a result of their insurance policy terms or various state legislations, are given generic drugs by their pharmacist when filling a prescription for brand-name drugs. Even patients who do not have insurance usually take generic drugs when available because they are cheaper than the equivalent name-brand drugs. Yet, while the Hatch-Waxman Amendments to the FDCA were implemented to allow cheaper generic manufacturers to enter the marketplace, they were not intended to override the FDCA's overall goal of maintaining both name-brand and generic drugs safe.⁴⁵

Recognizing the absurdness of its ruling, the Supreme Court noted that Congress is free to change the law.⁴⁶ To remedy the Court's ruling, consumer groups will likely combine resources to lobby Congress and/or the FDA to issue modified statutes and regulations to override the Court's decision. In the meantime, the *Mensing* and *Demahy* plaintiffs have filed a petition for rehearing with the Supreme Court arguing the Court failed to appreciate that the generic manufacturers were not compelled to sell these drugs and that, under both state and federal law, they could have ceased distribution of a drug they knew to be unsafe and ineffectively labeled. The Eighth Circuit, in its now reversed *Mensing* decision, issued a similar ruling when it held "The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."⁴⁷ Other practitioners have suggested that, since *Mensing* was only addressing the regulations prior to the implementation of the 2007 Amendments, perhaps the Court's ruling can be limited to injuries that arose prior to 2007. To date, however, no court has ruled on the validity of such arguments.⁴⁸ Only time will tell what legacy *Mensing* will leave behind and whether it will be extended to other products and regulations. In the meantime, however, it is clear that as a result of *Mensing*, many users of generic products may have no legal

recourse for injuries caused by inadequately labeled drugs while users of the identical (yet more expensive) name-brand drugs will have legal recourse. If anything, the Supreme Court's *Mensing* decision gives further confirmation to Judge Sturgess' comment that "Justice is open to everyone in the same way as the Ritz Hotel."⁴⁹

Endnotes

1. Napoleon in a letter to Abbe' de Pradt (1812).
2. U.S. Const. Art. VI, cl.2.
3. *Gibbons v. Ogden*, 22 U.S. 1, 211 (1824).
4. *Sprietsma v. Mercury Marine*, 123 S.Ct. 518, 528 (2002).
5. *Levine*, 129 S.Ct. at 1195-96.
6. George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); and MILTON FRIEDMAN, *FREE TO CHOOSE: A PERSONAL STATEMENT* 201 (1990).
7. FRIEDMAN, *supra* note 6, at 197.
8. See e.g., Terry J. Allen, *High Court May Immunize Big Pharma.*, IN THESE TIMES, September 9, 2008 ("The architect of FDA's preemption policy is Daniel Troy."); Michael Kranish, *FDA Counsel's Rise Embodies US Shift*, BOSTON GLOBE, December 22, 2002 (Troy's FDA stint "certainly does raise the question of the fox in charge of the chicken coop"); *Levine*, 129 S.Ct. at 1203, n.11 ("The Office of Chief Counsel ignored the warnings from FDA scientists and career officials" regarding the illegitimacy of the agency's new pro-preemption policy); see also *Mason v. SmithKline Beecham*, 596 F.3d 387 (7th Cir. 2010) (discussing history of preemption including that after 2001 (Bush's Presidency) the FDA began to revise its regulations to bolster the drug manufacturer's preemption defense).
9. 21 U.S.C. § 355(a), (b).
10. 21 U.S.C. §§ 355(b), (d).
11. 21 C.F.R. §§ 201.56, 201.57.
12. 21 U.S.C. § 355(j).
13. 57 Fed. Reg. 17950, 17951 (1992) (describing Hatch-Waxman Act).
14. 21 U.S.C. § 355(j).
15. 21 U.S.C. § 355(j)(2)(A)(v).
16. 21 C.F.R. § 314.80(a) (name brand manufacturers); 21 C.F.R. § 314.98(a) (generic manufacturers).
17. 21 C.F.R. § 314.81(b)(2) (name brand manufacturers); 21 C.F.R. § 314.98(c) (generic manufacturers).
18. 21 C.F.R. § 201.57(e) (for current drugs); 201.80(e) (for older drugs).
19. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2011); 21 C.F.R. § 314.70(c)(2)(I) (2000).
20. 21 C.F.R. § 314.97.
21. *Levine*, 129 S.Ct. at 1198-99 & n.6.
22. *Levine*, 129 S.Ct. at 1200.
23. *Levine*, 129 S.Ct. at 1195 n.3.
24. *Levine*, 129 S.Ct. at 1197.
25. *Id.*
26. *Levine*, 129 S.Ct. at 1197-98 (emphasis added).
27. *Levine*, 129 S.Ct. at 1199.
28. *Id.*
29. *Levine*, 129 S.Ct. at 1202.
30. *Levine*, 129 S.Ct. at 1199, 1204.
31. *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Gaeta v. Perrigo Pharmaceutical Co.*, 630 F.3d 1225 (9th Cir. 2011).

32. *Mensing v. Wyeth*, 588 F.3d 603 (8th Cir. 2009); *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010).
33. The state laws at issue were the laws of the plaintiffs' home state — Minnesota law for *Mensing* and Louisiana law for *Demahy*.
34. *Mensing*, 131 S.Ct. at 2575-76.
35. *Id.* at 2579.
36. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1009 (2008); *Christensen v. Harris County*, 120 S.Ct. 1655, 1663 (2000) ("deference is warranted only when the language of the regulation is ambiguous" and further holding that "[t]o defer to the agency's position would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation.>").
37. *Citizen's United v. Federal Election Comm'n*, 130 S.Ct. 879, 898-99 (2010).
38. For a more detailed analysis of the First Amendment argument please see the *amicus* brief submitted by the National Coalition Against Censorship in *Mensing* — available at: http://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/09-993_respondent_amcu_national_coalitionagainstcensorship.authcheckdam.pdf.
39. *Mensing*, 131 S.Ct. at 2588-90 (Sotomayor, J., dissenting).
40. *Mensing*, 131 S.Ct. at 2579-81.
41. *Levine*, 129 S.Ct. at 1198.
42. *Levine*, 129 S.Ct. at 1198; *Rice v. Norman Williams Co.*, 102 S.Ct. 3294, 3299 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute.>").
43. *Mensing*, 131 S.Ct. at 2581.
44. *Id.*
45. See e.g. *Demahy*, 593 F.3d at 448-49 ("nothing about the Hatch-Waxman Amendments and their goal of cheaper drugs obviates the concomitant prescription that all drugs even cheaper ones remain safe.>").
46. *Mensing*, 131 S.Ct. at 2581.
47. *Mensing*, 588 F.3d at 611, *rev'd*, 131 S.Ct. 2567.
48. Outside of the legal arena, pundits have suggested that pharmacists should be required to provide each consumer with a leaflet informing them that, by accepting generic drugs, they are giving up their right to legal recourse should they ever be injured.
49. Judge Sturgess (July 22, 1928). ■

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