Logical Contradiction Doctrine: Buckman for Textualists

PLAC HLTh Group Webinar Series

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Buckman Basics

Defendant allegedly misrepresented the "intended use" of a medical device to the FDA, resulting in its § 510(k) approval

- FDA never found fraud, and supported defendant with an amicus brief in the Supreme Court
- Fraud on the FDA claims would allow a state common-law jury to ignore an in-force FDA decision that a plaintiff claims was fraudulently obtained

For obvious reasons such claims "inevitably conflict" with FDA authority

Two chief grounds for implied preemption in Buckman

- Private plaintiffs cannot sue to enforce the FDCA – § 337(c); no traditional state-law tort for fraud against federal government agencies of any sort
- As a practical matter, unpredictable state-law fraud claims would hinder FDA decision-making by encouraging regulated entities to flood FDA with unnecessary paper

Obstacle Implied Preemption

***Savage v. Jones*, 1912 (involving an FDCA predecessor):**

> "For when the question is whether a Federal act overrides a state law, the entire scheme of the statute must . . . be considered, and [w]hat . . . must be implied is of no less force than that which is expressed. If the purpose of the act cannot otherwise be accomplished − if its operation . . . else must be frustrated and its provisions be refused their natural effect − the state law must yield to the regulation of Congress."

***Hines v. Davidowitz*, 1941, relied on *Savage* to formulate called "obstacle" or "purposes and objectives preemption**

> "Our primary function is to determine whether . . . [state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Although not using this precise phraseology, *Buckman*'s preemption analysis focused on problems that fraud on the FDA claims would cause the FDA

Buckman – Fraud on the FDA Claims Interfere with the FDCA's Regulatory Scheme

FDA has tools to enforce § 510(k) disclosure requirements, and to punish false statements

FDA balances device marketing requirements against benefits of practice of medicine involving off-label use

Fraud on the FDA claims discourage submission of products with beneficial off-label uses

Disclosures being second-guessed in mass-tort litigation encourages over-submission of information to FDA

Wading through the additional paper would waste FDA time and effort, and delay clearance/approval of new products

Buckman – Private Plaintiffs Cannot Bring Fraud on the FDA Claims

States do not police fraud against government agencies

Defendant's dealings with the FDA were pursuant to statutory requirements

The FDCA provides (with irrelevant exceptions) that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. § 337(c)

All actions for allegedly defrauding the FDA implicate the enforcement mechanisms of the FDCA

Section 337(a) provides "clear evidence" of congressional intent that the FDCA should "be enforced exclusively by the federal government"

Agency fraud claims "exist solely by virtue of the FDCA disclosure requirements" so the FDCA is a "critical element" of such causes of action

Justice Thomas and *Buckman*

Justice Thomas concurred in *Buckman*

Although the FDA knew of the claimed fraud, it did nothing to remove the device from the market

- Therefore no causation

Causation is dependent on the details of FDA regulations for medical devices

While *Buckman* "does not fit neatly into our pre-existing pre-emption jurisprudence," it is accurate to call the claim preempted because the FDA has not acknowledged the fraud

Would allow fraud on the FDA claims if FDA had found fraud

- No second-guessing FDA decisions
- No speculation about contrafactual FDA actions

Majority leaves no alternative ground for redress even where FDA found fraud and none of the adverse consequences would occur

Justice Thomas and Obstacle Preemption − Early Decisions

1995 – *Myrick* − Tort preemption, unexceptional analysis

- **Lack of any federal standard meant that statute had nothing to say on the subject at all; no federal objective to undermine**

2000 – *Geier* – Tort Preemption, joins a dissent (by Stevens),

- **For the first time embraces description of obstacle preemption as a "freewheeling judicial inquiry into whether state law is in tension with federal objectives"**
- **Follows a presumption against preemption**

2001 – *Buckman*

2002 – *Rush Prudential* – Dissenting opinion in favor of preemption

- **Still follows obstacle preemption in ERISA case**

Justice Thomas and Obstacle Preemption − Continuing Evolution

2003 – *PhRMA* – Concur in result

- **Criticizes "the impossibility of defining 'purposes' in complex statutes . . . the concomitant danger of invoking obstacle pre-emption based on the arbitrary selection of one purpose to the exclusion of others"**

2005 – *Bates* – Tort preemption, concurring in part

- **Discusses his "increasing reluctance to expand federal statutes . . . through doctrines of implied preemption," repeats "freewheeling" quotation**

2008 – *Warner-Lambert* – Tort preemption, *per curiam* 4-4 split on whether *Buckman* preempts a fraud on the FDA-based exception to a state-law compliance provision

- **While votes are not announced, Thomas is believed to be the 4th anti-preemption vote**

2009 – *Levine* – Tort preemption, concur in judgment of no preemption

- **Rejects "purposes and objectives" preemption outright as a "doctrine[] that wander[s] far from the statutory text"**

Justice Thomas on Implied Preemption Since Rejecting Obstacle Preemption I

2009 – *Hayword* – Dissent (+3)

- **Supremacy Clause gives only "law" preemptive effect, not "extratextual considerations of . . . purposes"**
- **"A sweeping approach to pre-emption based on perceived congressional purposes leads to the illegitimate − and thus, unconstitutional − invalidation of state laws"**

2011 – *Williamson* – Tort preemption, concur

- **Obstacle preemption is "wholly illegitimate"**
- **"[P]re-emptive effect [should] be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text"**
- **"[P]re-emption must turn on the text of a federal statute or the regulations it authorizes"**
- **Preemption cannot be based on "conceptions of a policy which Congress has not expressed," nor "agency musings and Government litigating positions," nor "psychoanalysis" of regulators**

Justice Thomas on Implied Preemption Since Rejecting Obstacle Preemption II

2011 – *Mensing* – Tort preemption, writes majority opinion (save one subsection on Supremacy Clause as "*non obstante" provision)*

- **Compare federal and state law, "do[es] not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless"**

2012 – *Arizona* – Dissent

- **"[P]re-emptive effect is to be given to congressionally enacted laws, not to judicially divined legislative purposes"**

Justice Thomas' Alternative Implied Preemption Model I

2011 – *Mensing* – Tort preemption, plurality opinion

- **Supremacy Clause is a "*non obstante*" provision whereby federal law "impliedly repeal[s] conflicting state law"**
- **"[C]ourts should not strain to find ways to reconcile federal law with seemingly conflicting state law"**
- **no "contingent supremacy" − manufacturers not required "continually to prove the counterfactual conduct of the FDA" and others**

2013 – *Hillman* – Concur

- **"[A] court should find pre-emption only when the 'ordinary meaning' of duly enacted federal law 'effectively repeal[s] contrary state law'"**

2015 – *Oneok* – Concur

- **"[P]re-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text"**

Justice Thomas' Alternative Implied Preemption Model II

2016 – *Gobeille* – Concur

- **Questions ERISA preemption because preempts "substantial areas of traditional state regulation"**

2019 − *Lipschultz* – Concur in denial of *certiorari*

- **Reaffirming *non obstante* status of Supremacy Clause; regulators cannot "make 'Law' by declining to act"**

Justice Gorsuch Also Rejects Obstacle Preemption

Virginia Uranium – Plurality

- **"No more . . . can the Supremacy Clause be deployed here to elevate abstract and unenacted legislative desires above state law**
- **Only federal laws 'made in pursuance of' the Constitution, through its prescribed processes of bicameralism and presentment, are entitled to preemptive effect"**
- **"Trying to discern what motivates legislators . . . invites speculation"**
- **"[I]n piling inference upon inference about hidden legislative wishes we risk displacing the legislative compromises actually reflected in the statutory text"**

Lipschultz – Gorsuch & Thomas, concurring in denial of certiorari

- **"[D]oubtful whether a federal policy . . . is 'Law' for purposes of the Supremacy Clause. Under our precedent, such a policy likely is not final agency action"**
- **"[T]he Supremacy Clause "requires that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text" (quoting Thomas in *Levine*)**

Kansas − Gorsuch & Thomas, concurring, wrote separately

- **[R]eiterat[ing] [their] view that we should explicitly abandon our 'purposes and objectives' pre-emption jurisprudence"**
- **Repeat *non obstante* and "logical contradiction" reasoning**

Albrecht – Justice Thomas Applies His "Logical Contradiction" Model

Albrecht – Concur

- **"I remain skeptical that "physical impossibility" is a proper test for deciding whether a direct conflict exists between federal and state law"**
- **"[F]ederal law pre-empts state law only if the two are in logical contradiction"; "Sometimes, federal law will logically contradict state law even if it is possible for a person to comply with both"**
- **"[I]f federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands" even if "an individual could comply with both by electing to refrain from the covered behavior"**
- **"Absent a federal statutory right to sell a brand-name drug with an FDA-approved label, FDA approval "does not represent a finding that the drug, as labeled, can never be deemed unsafe"**
- **"[N]either agency musings nor hypothetical future rejections constitute pre-emptive 'Laws' under the Supremacy Clause"; "hypothetical agency action is not 'Law'"**
- **FDA complete response "letter was not a final agency action with the force of law, so it cannot be 'Law' with pre-emptive effect"**
- **Defendant "points to no statute, regulation, or other agency action with the force of law that would have prohibited it from complying with its alleged state-law duties"**

The Problem *Buckman* Poses for Defendants

In product liability cases, the recent Supreme Court has been closely divided on implied preemption issues, particularly in tort cases

- ***Mensing* and *Bartlett* were both 5-4**
- **In *Albrecht* the Court avoided the ultimate preemption issue – Thomas reached it and rejected preemption**
- **The Court split 4-4 on a *Buckman* issue in *Kent* (Roberts recused)**
- ***Buckman* not mentioned at all in *Albrecht*; only by 3-justice dissent in *Levine***
- **Non-drug defendants have not had an "obstacle"-based implied preemption win since *Geier***

Addition of Justice Barrett may have improved preemption prospects, but too early to tell

Defendants cannot reasonably expect to win on *Buckman*/implied preemption grounds in tort cases while losing Thomas and Gorsuch

Buckman's "No Private FDCA Enforcement" Prong as a Logical Contradiction

Given U.S.C. § 337(a), providing that "all proceedings for . . . enforcement" of the FDCA "shall be by and in the name of the United States," the *Buckman* prohibition against plaintiffs suing over alleged FDCA violations fits easily

- **It is express statutory language, passed by Congress**
- **Because the Supremacy Clause, as a *non obstante* provision, impliedly repealing conflicting state law, no presumption against preemption requires courts to strain to reconcile preemptive federal law with disguised state law FDCA enforcement attempts with FDCA violation allegations as a critical element**
- **The ordinary meaning of § 337(a) is exactly as *Buckman* interpreted it – "clear evidence" that Congress did not intend any private, or unauthorized state, enforcement of the FDCA no matter how presented**
- **This could produce a better result than *Lohr***
- **Conflict preemption of all forms of attempted private FDCA enforcement follows as a logical contradiction with the statutory text"**

Buckman's Preemption of FDA Fraud Claims Prong as a Logical Contradiction I

Fraud on the FDA is a state-law collateral attack on FDA decision-making

- **It impugns the information upon which the FDA acted**
- **It would allow state law to ignore whatever in-force FDA decision is being challenged**

State-law claims that collaterally attack in-force FDA decisions logically contradict, and are inherently incompatible with, the FDA decision being challenged

FDA decisions, such as the product approval at issue in *Buckman*, are "law" as understood by the Supremacy Clause – final orders of the agency Congress charged with administering the FDCA

- **Attacks on in-force orders, such as product approvals, are fundamentally different from the letter at issue in *Albrecht*, which was subject to additional administrative action**
- **An FDA decision qualifying as "law," and therefore preemptive under the Supremacy Clause, cannot lose its preemptive effect by virtue of any state-law challenge, since federal law is supreme**

Buckman's Preemption of FDA Fraud Claims Prong as a Logical Contradiction II

Fraud on the FDA claims would create "contingent supremacy"

- **Any causation element involves allegations of counterfactual conduct by the FDA, in the event the agency had received more or different information**

Federal law, the FDCA as administered by the FDA, gives a person the right to engage in certain conduct

- **Should state law prohibit conduct, such as marketing a product allegedly "fraudulently" FDA approved, state and federal law would be contradictory**
- **That contradiction remains even if inaction (stop selling) could theoretically comply with both federal and state law**

Defendants Need To Articulate *Buckman*-Preserving Preemption Arguments Early On

Defendants who only argue *Buckman* as an objectives implied preemption case in the district court run the risk of waiver

- **A defendant that wins with a conventional *Buckman* preemption argument may argue in the alternative on appeal any position that supports affirmance**
- **An appellant defendant is bound by waiver rules to argue only those positions preserved in the district court**
- **For example, the defendant in *Kent* lost in the Court of Appeals, thus, if *Kent* were on appeal today the defendant could not assert implied preemption on a ground that Justices Thomas and Gorsuch could accept**

Assuming that the three remaining Supreme Court "liberal" justices continue to oppose preemption in tort cases, a manufacturer of prescription medical products cannot prevail on an objectives preemption-based interpretation of *Buckman*

- **Such a result would allow plaintiffs broad leeway to bring "state-law" claims that are simply claims that defendants violated the FDCA**
- **Such a result would allow plaintiffs to make arguments that defendants should never have developed and marketed FDA-approved products**

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