

CAPITOL STREET

April 4, 2025

BI Oral Arguments: Excise Taxes May Sway Appellate Judges

IRA Litigation Update & Tracker

Relevant Companies



»» Our Take & Next Up

Yesterday, appellate judges appeared sympathetic to Boehringer Ingelheim’s excise tax argument, but skeptical of the constitutional arguments at large ([here](#)). We note that pharmaceutical companies have struggled at the district court level to make their case. Judges pushed back on BI’s arguments involving the 1st amendment (Judges noted “manufacturers can still go on tv”) and the 5th amendment takings clause. They pointed out that the government is trying to obtain prices as a market participant, which may be an antitrust issue but there is no antitrust liability if you are the government. As a reminder, Jardiance (type 2 diabetes) is BI’s top selling pharmaceutical drug (partnered with Eli Lilly) and is set to face negotiated prices in 2026.

- **The issue of the excise taxes stood out as a potential industry winning point.** On unconstitutional conditions, judges seem to understand BI’s arguments best in context of the excise tax as being excessive. However, they are not completely confident in the argument because it appears that BI would make the same constitutional case without the excise tax in place.
- **Boehringer Ingelheim argued on several different fronts: 1st & 5th Amendment, APA violation, and Unconstitutional Conditions.**
 - 1st Amendment:** co. alleges that the IRA forces BI to express the Government’s message that the program involves “negotiations” resulting in an “agreement” on a “maximum fair price” for Jardiance.
 - 5th Amendment, takings clause:** co. alleges that the per se taking occurs without CMS itself seizing Jardiance products as a price can not be accessed without access to the product.
 - APA:** co. alleges that the Manufacturer Agreement is invalid because it is a legislative rule that was promulgated without the notice-and-comment procedures required by the APA.
 - Unconstitutional conditions:** co. alleges that the CMS is exercising regulatory power and economic coercion to make companies comply with negotiations.

UP NEXT: Oral arguments for NVO and NVS are scheduled for April 8. A slew of decisions (MRK, BMY, JNJ, AZN) are still expected to be released “any day now.” We note that judges do not like ruling on the adequacy of Medicare reimbursement. They largely consider Medicare participation voluntary regardless of the payment rate (*Garelick v. Sullivan*). However, previously, a Connecticut court ruled against BI, stating that the company’s participation in the negotiation is voluntary.

»» Key Points

Capitol Street IRA Litigation Scorecard

	Link	Next Up	1st Amdt	5th Amdt	8th Amdt	Separation of Powers	APA violation	10 Drug Limit	Unconstitutional Conditions
Merck	DC District Court case here	Waiting on a decision any day now	X	X					
Bristol Myers Squibb	3rd Circuit case here	Waiting on a decision any day now	X	X					X
J&J	3rd Circuit case here	Waiting on a decision any day now	X	X					X
AstraZeneca	3rd Circuit case here	Waiting on a decision any day now		X			X		
Novo Nordisk	3rd Circuit case here	Oral Arguments 4/8/25	X	X		X	X	X	
Novartis	3rd Circuit case here	Oral Arguments 4/8/25	X	X	X				X
Boehringer Ingelheim	2nd Circuit case here	Oral Arguments Completed	X	X			X		X
Chamber of Commerce	6th Circuit case here	Briefing Ongoing	X	X	X	X			
PhRMA, NICA, GCCA	5th Circuit case here	Govt's Cross Motion for Summary Judgement Due 4/21/25		X	X	X	X		

	Link	Next Up	1st Amdt	5th Amdt	8th Amdt	Separation of Powers	APA violation	10 Drug Limit	Unconstitutional Conditions
Teva	Filed in DC here	Government's Summary Judgment Motion Due		X			X		

Source: Georgetown Litigation Tracker, PACER, Capitol Street, 2025

Notes

- **1st Amendment, compelled speech.** Companies will be forced to communicate that they have “agreed” and endorse HHS’s “fair price” even when they do not agree with this characterization
- **5th Amendment, takings clause.** The Drug Negotiation program denies manufacturers their protected property interest without constitutional adequate procedures.
- **5th Amendment, due process.** No due process for negotiation - price controls with no protection
- **8th Amendment, excessive fines.** Negotiations institute "fines two-and-a-half to 25 times greater than the statutory penalty for criminal tax fraud"
- **Separation of Powers.** Congress has impermissibly delegated sweeping authority to a federal agency to implement price controls without providing a clear standard to guide the agency’s discretion or including other protections necessary
- **Administrative Procedure Act (APA) violation.** CMS's poor implementation violated the APA bc they didn't take public comment on important parts of the guidance. CMS definition of a Qualifying Single Source drug lumps different products together under different NDAs, Bona Fide marketing violation
- **Orphan Drug Act.** IRA undermines the Orphan Drug Act by reducing the market incentives for new drugs

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