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Germany in the Crosshairs: USTR's New Section 301 Drug Pricing Investigation and What It Means Alongside the Section 232 Pharmaceutical Tariff Regime

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KEY POINTS

- On June 18, USTR self-initiated a Section 301 investigation under the Trade Act of 1974 targeting Germany's pharmaceutical pricing policies, citing a 3.9x price disparity between U.S. and German consumers for brand-name drugs.
- The Section 301 investigation targets two specific German policies: confidentiality-conditioned discounts requiring a mandatory 9% price reduction and a 2026 draft law proposing variable rebates on patented medicines that industry estimates could reach 20% by 2030.
- Together, Section 232 tariffs of up to 100% on imported pharmaceuticals and the new Section 301 investigation form a coordinated two-statute strategy to pressure manufacturers to onshore production and foreign governments to raise reimbursement prices.
- Available Section 301 remedies include tariffs, import restrictions, retaliation on German goods, denial of trade benefits, or a negotiated resolution — and USTR has already requested consultations with Germany under Section 303(a) of the Trade Act.
- Written comments are due August 10, and a public hearing is set for September 22 — companies with data on pricing disparities, lost revenue, or R&D investment effects are well-positioned to shape the investigation's scope and remedy.

The United States Trade Representative (USTR) has opened a new front in the administration's campaign to reshape global pharmaceutical pricing. On June 18, 2026, the U.S. Trade Representative self-initiated an investigation pursuant to Section 301 of the Trade Act of 1974, as amended (Trade Act) (Section 301), targeting Germany's "persistent underpayment" for innovative pharmaceutical products. The investigation, filed under Docket Nos. USTR-2026-0463 and USTR-2026-0464, adds a powerful second trade law instrument to an already aggressive posture targeting the EU as a whole — one that, when read alongside the pharmaceutical tariffs proclaimed on April 2, 2026, under Section 232 of the Trade Expansion Act of 1962 (Section 232), signals a multistatute strategy to try to force trading partners to pay more for pharmaceutical research and development (R&D).

Pharmaceutical manufacturers, insurers, health care payers, and other stakeholders with German market exposure should act quickly: written comments are due by August 10, 2026, and a public hearing is set for September 22, 2026.

TWO STATUTES, ONE POLICY GOAL

SECTION 232 — THE FIRST STRIKE

As we detailed in our prior alert, Proclamation 11020 imposed tariffs of up to 100% *ad valorem* on patented pharmaceuticals and their ingredients under Section 232. The stated rationale: heavy U.S. reliance on imported pharmaceuticals threatens national security. The policy mechanism: a tiered tariff structure designed to pressure companies to onshore manufacturing and accept most-favored-nation (MFN) pricing agreements with the U.S. Department of Health and Human Services (HHS).

Critically, the Section 232 action is directed inward — it regulates what companies importing into the U.S. must pay. It is a supply chain and pricing lever aimed at manufacturers.

SECTION 301 — THE SECOND STRIKE

The new Section 301 investigation is directed outward — it targets Germany's government policies that suppress the price German consumers (and the German health system) pay for innovative pharmaceutical products. Under Section 301, the USTR may investigate and respond to foreign government acts, policies, or practices that are unreasonable or discriminatory and that burden or restrict U.S. commerce. Importantly, a practice need not violate international law to be "unreasonable" — it need only be unfair and inequitable.

Taken together, the two statutes form a pincer movement:

- **Section 232** pressures manufacturers to bring production to the U.S. and/or accept U.S.-favorable pricing.
- **Section 301** pressures Germany to raise its reimbursement prices, reducing the disparity in the price paid by the U.S. government as compared to the price paid by the German government.

This is not the first time USTR has deployed Section 301 in a high-profile, nontraditional context. In recent years, USTR has used Section 301 to address forced labor practices, digital services taxes, and supply-chain concerns — demonstrating that the statute's broad "unreasonable or discriminatory" standard is a flexible tool the administration is willing to use creatively.

WHAT USTR IS INVESTIGATING

THE CORE ALLEGATION

USTR's central charge is straightforward: U.S. consumers pay approximately 3.9 times as much as German consumers for brand-name drugs. This price gap, USTR argues, does not reflect fair market value — it reflects Germany's government-imposed pricing policies, which suppress reimbursement prices below what a competitive market would produce. The result is that, according to USTR, American patients disproportionately fund global pharmaceutical R&D, while German patients free-ride on that innovation at artificially low prices.

THE SPECIFIC POLICIES UNDER SCRUTINY

USTR has identified two initial targets:

1. **Confidentiality-Conditioned Discounts** Germany conditions the confidentiality of manufacturers' negotiated

pharmaceutical prices on certain criteria — including acceptance of a mandatory 9% price discount plus payment of additional administrative costs. In effect, companies that want their negotiated prices kept private must accept a structural discount on top of any negotiated rate.

2. **New Mandatory Rebate Legislation (2026 Draft)** Germany's Ministry of Health introduced draft legislation in 2026 designed to further reduce pharmaceutical spending. The proposal would impose mandatory variable rebates on patented medicines starting in 2027 — beginning at a fixed rate of 3.5% for the first half of 2027, then shifting to a dynamic variable rate tied to the difference between actual and target health insurance fund expenditures divided by innovative medicine sales. Industry estimates suggest this dynamic rebate could reach 20% by 2030.

USTR has expressly flagged this pending legislation as a "serious step backwards" and noted it as a key trigger for the timing of the investigation.

THE LEGAL STANDARD

Under Section 302(b)(1)(A) of the Trade Act, USTR must determine whether Germany's acts, policies, and practices are unreasonable or discriminatory, and burdensome on or restrictive of U.S. commerce.

An affirmative determination requires USTR to then decide whether to take action, and if so, what form that action takes. Available remedies are broad: tariffs, import restrictions, retaliation on German goods, denial of trade benefits, or a negotiated resolution. USTR has also requested consultations with the German government pursuant to Section 303(a) of the Trade Act — a required procedural step before any remedial action.

USTR is soliciting comments on a broad range of issues, including:

- The specific German pricing policies described above (confidentiality discounts; mandatory rebates).
- Other acts, policies, or practices of Germany related to pharmaceutical underpayment not already identified.
- Whether Germany's practices are unreasonable or discriminatory.
- The nature and extent of the burden on U.S. commerce.
- Whether Section 301(b) action is warranted — including tariff and nontariff actions.
- The extent to which Germany's practices shift global R&D costs onto American patients.

Companies with data on pricing disparities, lost revenue, R&D investment effects, or the specific legislative provisions at issue are well-positioned to submit comments that can shape the investigation's scope and ultimate remedy.

IMPLICATIONS FOR INDUSTRY

FOR PHARMACEUTICAL MANUFACTURERS AND LICENSORS

The Section 301 investigation creates both risk and opportunity. Companies already navigating the Section 232 tariff framework — evaluating onshoring plans, MFN pricing agreements with HHS, and transitional relief under Annexes II and III — now face a second set of policy dynamics. A negotiated resolution with Germany could raise German reimbursement prices, altering global reference pricing dynamics and affecting revenues in other markets that use Germany as a reference country. Companies should model these scenarios now.

Companies that submit comments can help shape the evidentiary record — including data on the specific impact of

German AMNOG (Arzneimittelmarktneuordnungsgesetz) pricing procedures, reference pricing, and the proposed 2026 rebate legislation — that will drive USTR's determination.

FOR INSURERS AND HEALTH CARE PAYERS

For U.S. health insurers and payers — including those operating or reinsuring in European markets — the investigation is a signal that the administration intends to use trade law to reshape global pharmaceutical price-setting norms. A successful Section 301 action that raises German prices could have ripple effects: higher German prices may reduce the downward pressure on U.S. prices that reference-price mechanisms currently create, but could also increase global drug costs borne by payers in other markets.

THE BROADER STRATEGIC CONTEXT

The convergence of Section 232 tariff pressure and this new Section 301 investigation marks a meaningful inflection point in how the U.S. is deploying trade law as a lever in global pharmaceutical policy. This is a coordinated, multistatute campaign with Germany as the named target and the broader EU pricing model squarely in scope.

The August 10, 2026, comment deadline is not a formality. USTR is actively building an evidentiary record, and the data submitted — or not submitted — will shape both the legal determination and any eventual remedy. Companies with German market exposure should also be stress-testing their commercial models against a range of outcomes: a negotiated settlement that raises German reimbursement prices and triggers reference pricing cascades elsewhere; tariff retaliation on German goods; or prolonged regulatory uncertainty across European markets.

The UK arrangement, cited by Ambassador Greer as a template, is instructive: countries that engage early with the administration's pricing objectives have obtained more favorable trade treatment. The implicit message to Germany — and to the EU more broadly — is that the cost of inaction may exceed the cost of negotiation.

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