

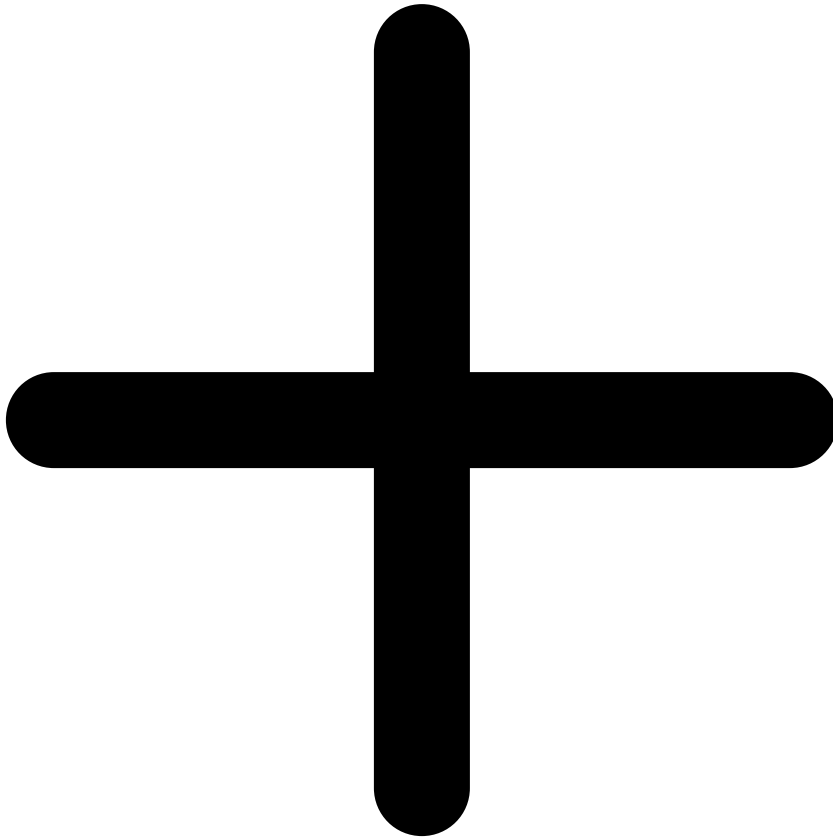
PUBLICATIONS | 04.29.2026

Explore the Latest Developments in Hatch-Waxman Litigation: Key Takeaways from the 2026 ACI Paragraph IV Disputes Conference

By Madison Garrett

Choate, Hall & Stewart's Madison Garrett attended the recent Paragraph IV Disputes Conference, convened by the American Conference Institute, on April 21-22, 2026 in New York, NY. In-house counsel, outside counsel and former regulators addressed recent developments and emerging trends from both brand and generic perspectives. Below are some of the key takeaways from the conference, representing the views of the conference speakers.

Potential Impacts of the Inflation Reduction Act





The Inflation Reduction Act (“IRA”) is predicted to have a significant impact on the industry and on biopharmaceutical IP litigation. Beginning this year, the U.S. Department of Health and Human Services (“HHS”) will set Medicare prices for eligible prescription medicines – starting with 10 qualifying drugs in 2026, 15 drugs in each of 2027 and 2028, and 20 drugs in 2029 and each year thereafter. Only “qualifying single source drugs” are subject to price setting under the IRA. Small molecule and biologic drugs may qualify if there is no approved and marketed generic and/or biosimilar for at least seven years (for small molecules) or eleven years (for biologics) after FDA approval or licensure. For both types, price setting goes into effect two years after a drug is selected.

The IRA is predicted to modify the incentives in traditional Hatch-Waxman and biosimilar litigation in the following ways:

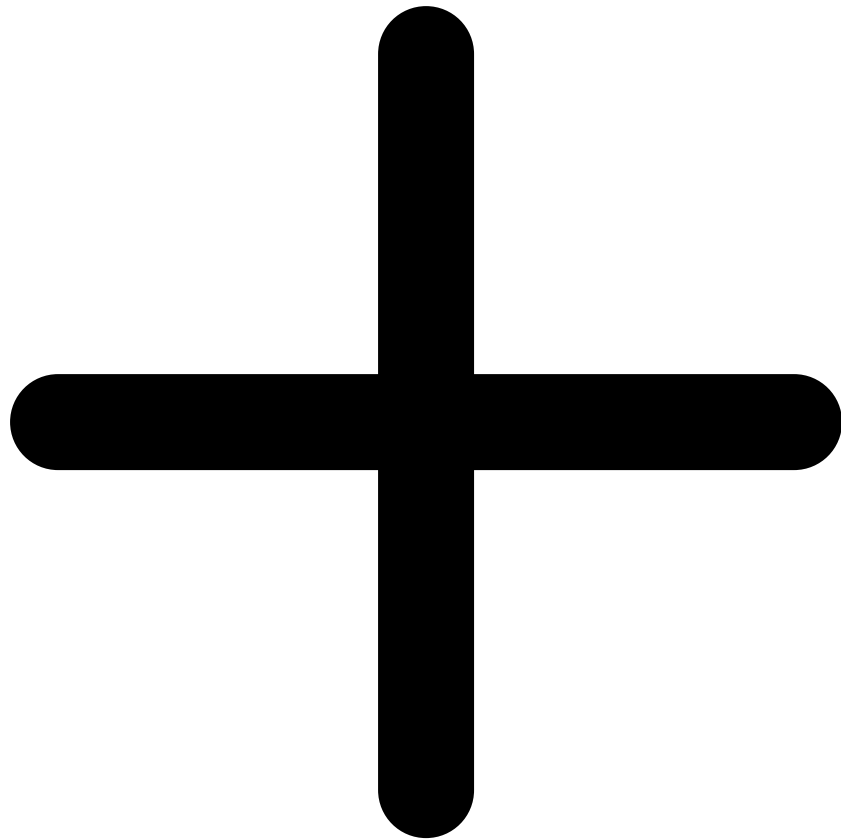
- Price setting provisions may sharply reduce the economic returns of the biopharmaceutical industry. On average, generics and biosimilars enter the market 13–14 years and 18 years, respectively, after FDA approval of the brand. The IRA markedly accelerates the time when a brand expects to face a reduction in revenue. This time frame is shortened from 13–14 years to 9 years (for small molecules) and from 18 years to 13 years (for biologics), potentially undermining the value of patent protection that would extend exclusivity beyond the shortened time frames.
- On the brand side, depending on the economics and market for particular drugs, brands may have more incentive to engage in early settlement because the existence of a generic or biosimilar on the market will remove the brand drug from consideration under the IRA. Brands should carefully compare the expected effect of price setting under the IRA versus the expected effect of entry by a generic competitor.

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- On the generic side, companies may have less incentive to develop generics and biosimilars due to uncertainty in pricing and the possibility that they would be subject to a price ceiling as set by HHS. If companies do choose to forego development of generics and biosimilars due to this new level of unpredictability in potential profit, we may see a resulting decline in Hatch-Waxman and/or biosimilar litigation.
- The IRA price setting timeline is shorter for small molecule drugs and longer for biologics. We may therefore see more biosimilar litigation, as compared to Hatch-Waxman litigation, in the future.

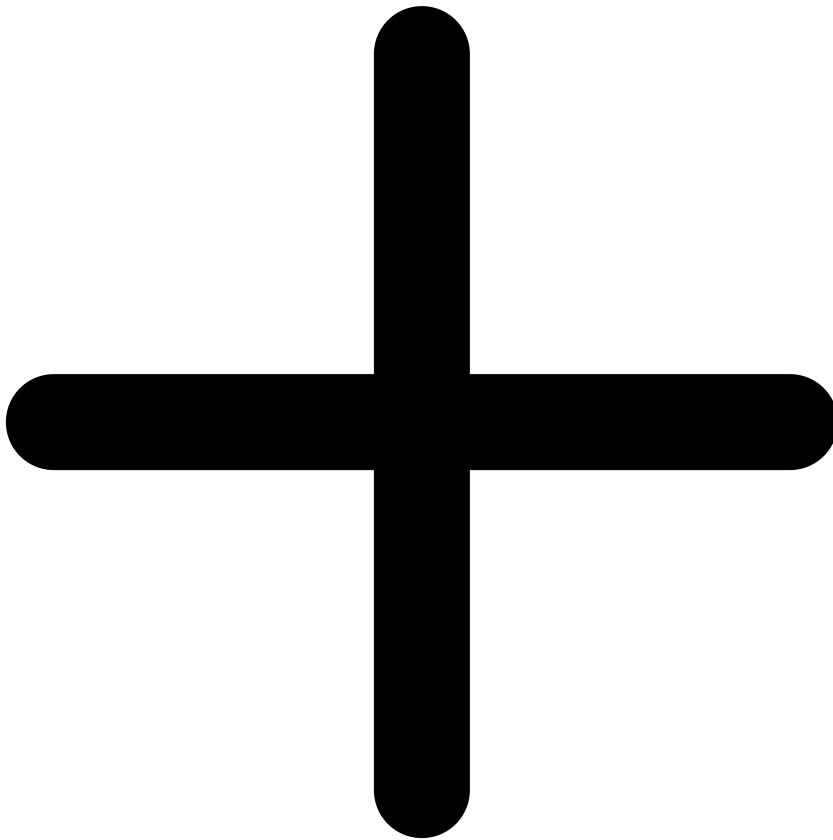
Latest § 112 Case Law





Panelists discussed the latest case law on written description and enablement, especially the Federal Circuit's recent decision in *Teva v. Eli Lilly*, No. 2024-1094 (Fed. Cir. April 16, 2026). In *Teva v. Eli Lilly*, the Federal Circuit considered patents related to methods of using humanized anti-CGRP antagonist antibodies to treat headaches. The Court found sufficient written description and enablement based on three central findings: the patents are not directed to the antibodies themselves, but rather to methods of use; a reasonable jury could have found that anti-CGRP antagonist antibodies were well-known and that methods of creating "humanized" versions of antibodies were routine; and Eli Lilly did not dispute that the specification discloses all humanized anti-CGRP antagonist antibodies treat headache. As several panelists noted, this opinion is based on a highly specific set of facts that will not be applicable across the board. Other panelists expressed interest, however, pointing to the Federal Circuit's distinction between method-type genus claims and composition-type genus claims, and predicting that this distinction could have some importance moving forward.

Supreme Court Consideration of Carve-outs and Induced Infringement





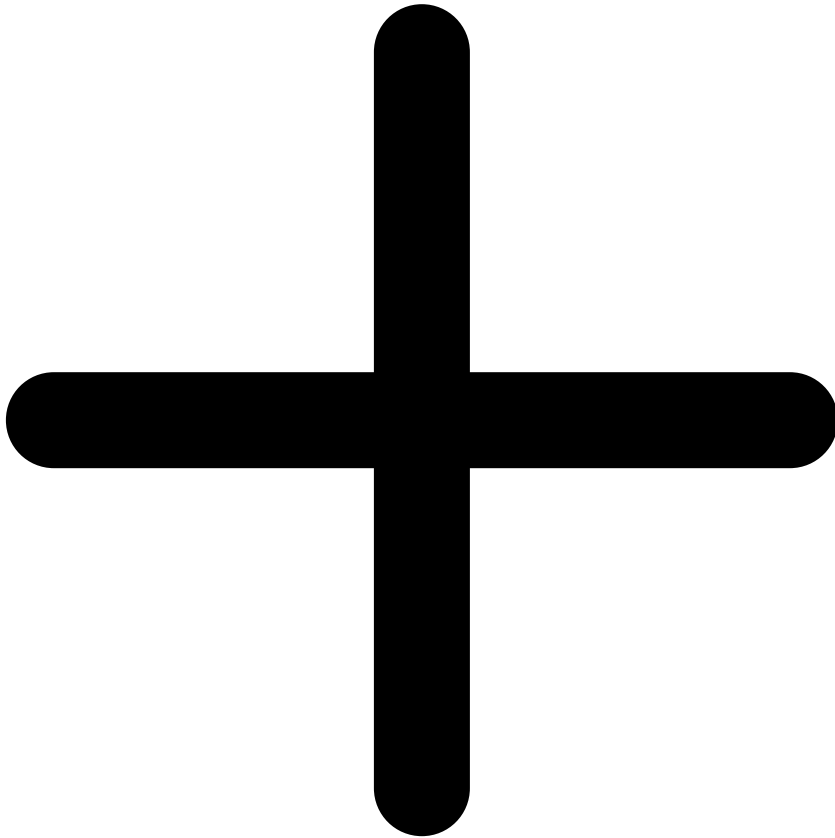
Label carve-outs (also known as “skinny labels”) are receiving attention ahead of Supreme Court oral argument in *Hikma v. Amarin*, which is scheduled for Wednesday April 29, 2026. This case has the potential to affect the doctrine of induced infringement, which requires both (1) underlying direct infringement and (2) a specific intent by a defendant to encourage infringement. In *Hikma v. Amarin*, the Supreme Court is poised to address the second prong. As brief background, Amarin’s brand drug Vascepa® was originally approved to reduce triglyceride levels in adults with severe hypertriglyceridemia (“SH indication”) and was later approved to reduce cardiovascular risk (“CV indication”). Amarin has patents directed to the CV indication. Hikma’s label for its generic product includes the SH indication but carves out the patented indication for CV. The Supreme Court will consider whether Amarin sufficiently pleaded induced infringement. Amarin’s allegations point to (1) Hikma’s label, which carves out the patented CV indication but also (i) omits a limitation of use regarding cardiovascular disease which Amarin included in its original SH indication label and (ii) includes a warning as to side effects for the patented use; and (2) public statements made by Hikma, which touted its product as a “generic equivalent” to Vascepa®, and stated the brand’s sales figures, which were “largely attributable to the off-label CV indication.”

While the Supreme Court may focus on the 12(b)(6) motion to dismiss standard, rather than wading into the doctrine of induced infringement, industry observers anticipate that the Supreme Court will offer at least some substantive guidance. Brand and generic companies alike are eagerly awaiting the April 29 oral argument and the subsequent Supreme Court decision. For brands, a favorable ruling for Hikma may reduce incentives to develop new uses for approved drug products if generics are permitted to indirectly promote patented uses. Additionally, if the Supreme Court tightens the standard for induced infringement, brands may

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have a harder time enforcing method-of-use patents through skinny-label claims and might consider additional, or alternative, intellectual property protection strategies. On the other side, generics believe a ruling in favor of Amarin would allow brands to weaponize routine marketing statements and would subvert the Hatch-Waxman framework, creating uncertainty even where the generic carves out patented indications. www.choate.com

Recent Updates at the FDA and USPTO





The FDA and USPTO have separately implemented substantive changes over the last year.

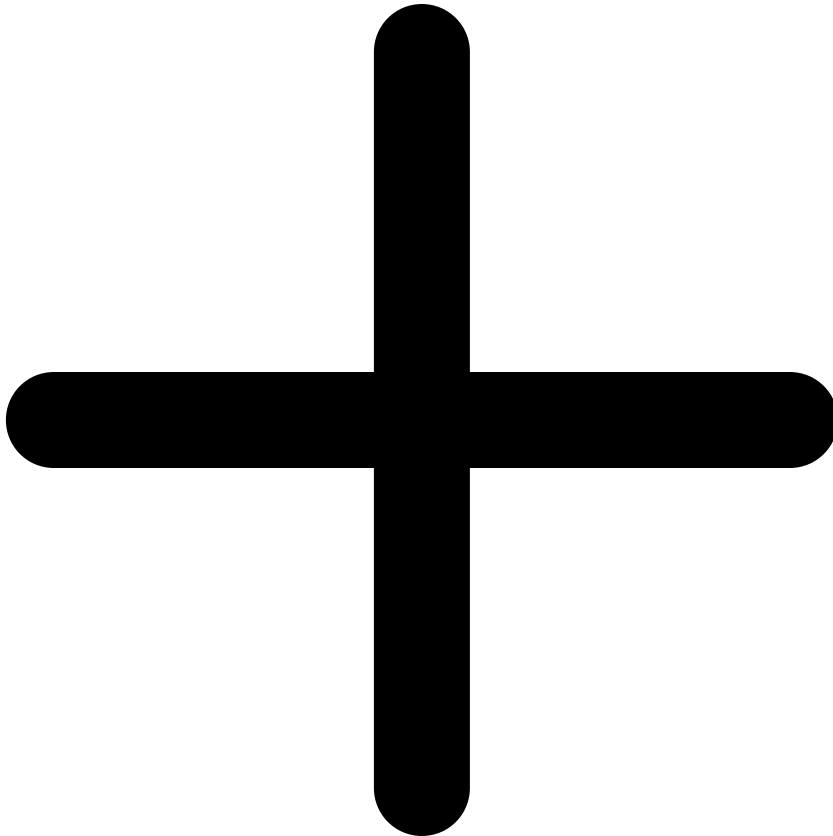
As part of its push for “radical transparency,” the FDA has begun publicly releasing Complete Response Letters (“CRLs”) through a centralized database, announced plans to publish CRLs in real time, and issued reminders to more than 2,200 companies and researchers regarding clinical trial result disclosure obligations. In addition, pursuant to a new federal law, during the ANDA process the FDA will provide earlier and more detailed feedback on whether a proposed generic drug is qualitatively and quantitatively the same as the reference listed drug, including identification of differing ingredient(s) and the extent of any quantitative variation. These measures aim to improve efficiency by reducing information gaps. Regulators also hope these changes will increase industry accountability, prompting pharmaceutical companies to ensure the accuracy of public statements. Pharmaceutical companies should also consider the potential for heightened shareholder litigation or stock price volatility following adverse FDA decisions or clinical trial results.

The current USPTO Director states that his primary goal is to ensure patents are “born strong” by improving “input quality,” including by providing incentives to disclose prior art and by using AI to strengthen the examination process. Remarkably, in post-grant proceedings, the USPTO has centralized institution authority at the Director level: the Director now makes all decisions about whether to institute a proceeding, and a PTAB panel is assigned only if institution is granted, at which point the panel conducts the trial. Additionally, “summary notices” are now issued in place of substantive institution decisions – in the name of eliminating both “referral-signal” bias and any interest of the Board in filling its own docket. The new summary notices provide parties with less insight into why a petition was granted or denied. Meanwhile, institution decisions are made (whether explained or not) based on

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new discretionary factors such as “Board workload” and “settled expectations,” a factor that calls for enhanced scrutiny where the challenged patent has been in force for at least six years. www.choate.com

“America First” Initiatives





The current administration's "America First" initiatives undoubtedly have an impact on the pharmaceutical industry, including through tariffs, onshoring, and recent changes at the FDA and USPTO. On April 2, 2026, the Administration released a proclamation announcing (i) no new tariffs for generic medicines (though the Secretary of Commerce will continue reviewing and is to inform the President within one year of any circumstances that indicate a need to take action), and (ii) up to 100% tariffs on patented pharmaceuticals, subject to country- and company-specific reductions. Company-specific reductions include reduction to a 20% tariff for companies that have "onshoring plans" approved by the Secretary of Commerce, and reduction to 0% for companies that have entered into a "Most Favored Nation" pharmaceutical pricing agreement with HHS. Country-specific reductions include a 15% tariff for products of the EU, Japan, Korea, Switzerland, and Liechtenstein, and a 10% tariff for products of the UK. Panelists noted that to achieve the stated goals of addressing geopolitical risk and growing the domestic economy, it will be critical to set priorities and to assess vulnerability because it is not feasible to onshore all production, and trying to do so would likely create its own set of new risks.

Pharmaceutical companies should also keep in mind recent changes at the FDA and USPTO, including:

- The FDA's legislative proposal for Fiscal Year 2027 would allow companies that manufacture generic medications domestically to file Paragraph IV Certifications earlier, giving exclusivity rights to U.S. manufacturers.
- USPTO Director Squires's March 2026 memorandum identifies additional factors for discretionary denial of post-grant proceedings,

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including the extent to which accused products in parallel proceedings—and competing products made, sold, or licensed by the patent owner—are manufactured in the United States. www.choate.com

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