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Tips For Litigating Life Sciences Investigations At The ITC

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Pharmaceutical disputes are taking center stage for patent litigators in 2026 as the U.S. Supreme Court's unanimous decision in Hikma v. Amarin on skinny labels and induced infringement comes at a time of intense scrutiny over drug imports and pharma tariffs.

Indeed, U.S. drug prices are high, and many pharmaceuticals, biologics and active pharmaceutical ingredients are manufactured abroad. The U.S. Department of Commerce's May guidance addressing the 100% tariff issued in Proclamation 11020 reinforces that the intersection between intellectual property and trade is becoming increasingly important in the life sciences industry.

Yet a traditionally underutilized but powerful forum for life sciences companies has been the U.S. International Trade Commission.

This article provides a brief background of the ITC, and explores unique trends and practice tips for litigating life sciences investigations at this forum.

Brief Background

The ITC is a nonpartisan federal agency that has the authority to adjudicate unfair trade practices against imported articles that infringe U.S. statutory and nonstatutory IP rights.[1] The ITC is powerful because, if a violation is found, the ITC will order U.S. Customs and Border Protection to exclude entry of the infringing articles.[2] In 2025, the commission found a violation in around 54% of cases determined on the merits.[3]

ITC investigations move quickly and can go to trial in about eight-to-10 months after the complaint is filed. About 10% of investigations filed in 2025 involved pharmaceuticals and medical devices, and about 2.4% involved chemical compositions.[4]

Traditional Hatch-Waxman Act disputes are usually not litigated at the ITC, primarily because filing a complaint at the ITC does not trigger the 30-month statutory stay, but the ITC can be a strong and powerful forum for pharmaceutical and life sciences companies to litigate non-Orange Book and process patents, along with other causes of action, if the goal is to block competitors from importing their products into the U.S.

For biologics and biosimilars brand companies litigating against applicants that opted out of the patent dance, the ITC can be a quick and effective alternative forum to block competitors' products from being imported.

Trends and Practice Tips

Recent trends and developments at federal courts and the ITC carry unique considerations for life sciences companies and their litigation strategies. This section summarizes those trends and provides practical tips for companies to consider when litigating at the ITC.

Careful preinvestigation analysis and framing of the claims is important to avoid having the commission decline institution.

The threshold question to consider is what claims should be brought against which parties and how to frame the facts, as the commission can decline institution if the complaint fails to state a cognizable claim.

For example, in Amarin Pharma Inc. v. ITC in 2019, the U.S. Court of Appeals for the Federal Circuit affirmed the commission's decision not to institute an investigation following Amarin's filing of a complaint that alleged that its competitors were falsely labeling synthetically produced omega-3 products as "dietary supplements," rather than unapproved "new drugs" under the Federal Food, Drug and Cosmetic Act.[5]

The Federal Circuit held that Amarin's alleged violations of the Lanham Act and Tariff Act were precluded because adjudicating them would require the commission to resolve — in the first instance — an open regulatory classification question (drug versus dietary supplement) under the FDCA that the U.S. Food and Drug Administration itself had not answered.[6]

By contrast, in Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide in 2023, the commission instituted an investigation on Eli Lilly's complaint alleging that the respondents infringed its registered trademark for the drug Mounjaro and violated the Lanham Act's prohibition of false and misleading advertisements by claiming their products were FDA-approved or a generic form of Mounjaro.[7]

Eli Lilly's complaint included a section on why its claims are different from those in the Amarin case and should not invoke preclusion, and the FDA's preinstitution public interest comments also expressed no view on institution.[8]

Amarin's ITC complaint involved Vascepa — the same drug before the Supreme Court in Hikma v. Amarin. However, Amarin targeted different competitors at the ITC and asserted nonpatent causes of action, and its strategy is an example of how extensive and multifaceted legal battles in the pharmaceuticals and life sciences industry can be.[9]

Unlike in the Amarin case, where the commission would have had to resolve an open scientific and regulatory question, the Tirzepatide claims turned on straightforward factual inquiries settled by prior FDA determinations — placing them outside of Amarin's preclusion rationale and justifying institution.

In sum, these trends reinforce that careful preinvestigation analysis and thoughtful framing of the claims

are important to best position a complaint for institution and for companies to effectively use their IP to gain a competitive edge against different competitors. Because time is of the essence in ITC investigations, tackling issues up front can also improve chances of institution.

The safe harbor defense might not preclude institution of an ITC investigation — both timing and venue are important considerations for parties in developing parallel litigation strategies.

The ITC recognizes the safe harbor defense under Title 35 of the U.S. Code, Section 271(e)(1), but whether the defense has merit is fact-specific, and each accused activity is evaluated separately.[10]

Last year, in Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof, BioMarin Pharmaceutical Inc. initially named various entities of Ascendis Pharma Inc. as proposed respondents, along with Ascendis' drug substance manufacturer and supplier, Wacker Biotech GmbH.[11]

BioMarin alleged that Wacker imported an amount of drug substance that exceeds what would fall within the safe harbor.[12] Both Ascendis and Wacker argued against institution or for adjudication under the ITC's 100-day program.[13] The commission denied these requests because "[t]he suggested safe harbor analysis may be too complex to be decided within 100 days of institution" and instituted an investigation.[14]

This investigation is not only a good example of how the scope of the safe harbor defense is still evolving at the ITC, but also why timing and choice of venue are important for parallel litigations.

BioMarin filed its ITC complaint the day after Ascendis filed a new drug application with the FDA for its own drug, and less than two weeks later, Ascendis filed a complaint for declaratory judgment of noninfringement in federal district court, asserting, among other things, that its activities are exempt under the safe harbor.[15]

Ascendis purposefully did not move for a mandatory stay within 30 days after its complaint was filed, but moved for a speedy hearing on its safe harbor defense.[16]

That hearing, however, never happened because more than 30 days after its complaint was filed, Ascendis voluntarily dismissed and refiled a complaint that is nearly identical — "except that it pleads non-infringement broadly, which includes the safe harbor defense"[17] — and the district court entered a discretionary stay.[18]

A few weeks before the ITC trial started, BioMarin moved to lift the stay,[19] but the U.S. District Court for the Northern District of California denied the motion, stating that by choosing the ITC, BioMarin relinquished its ability to seek preliminary injunctive relief from a district court.[20]

Ascendis eventually dropped this defense at the ITC because its product launched commercially in the U.S. on April 6 this year, but the fact-specific nature of this defense means that parties that raise it should be prepared to take this issue to trial.[21]

In February, the proposed respondents in Certain Pertuzumab Biosimilars, Including Those Made by Certain Methods of Manufacturing, the Active Ingredient Thereof, and Products Containing the Same filed a similar request, and argued that their facts are different from BioMarin's investigation because the latter involved a new drug application and "the importation and unfair act allegations were far

broader." [22]

The fate of these arguments in this biosimilars investigation remains to be seen, as the commission granted the complainant's third request to postpone institution to June 17, and on June 8, the complainant filed another request to extend the deadline to June 26.[23]

Regardless, parties should expect to see a rise in disputes involving the safe harbor defense in future life sciences investigations, and be wary that courts are holding parties accountable for strategic choices on when and where to litigate these issues.

Smaller companies should now find it easier to satisfy the domestic industry economic prong requirement and, if named as proposed respondents, they can consider filing an ITC countersuit.

Standing to sue in the ITC traditionally was limited to only IP owners that could demonstrate significant monetary investments in the U.S. specifically relating to manufacturing or research and development, engineering and related technical activity.

A pair of Federal Circuit decisions in 2025, Lashify Inc. v. ITC and Wuhan Healthgen Biotechnology Corp. v. ITC, demonstrate that IP owners that do not manufacture in the U.S. and may otherwise be deemed as mere importers can now satisfy the ITC's previously daunting domestic industry economic prong requirement by relying on their significant investments in "sales, marketing, warehousing, quality control, or distribution"[24] and, under "a holistic review," small market segments can satisfy this requirement.[25]

Coupled with the Department of Commerce's recent guidance on company-specific onshoring agreements, the trend appears to strengthen and favor U.S. companies' ability to satisfy the domestic industry economic prong requirement, and stipulations on this issue may increase in future investigations as parties begin shifting their attention and resources to litigating other issues, like importation and the safe harbor defense.[26]

On the other hand, it should also be easier for proposed respondents to file countersuits at the ITC to level the playing field in settlement negotiations against complainants and benefit from the ITC's speed and go to trial within months, rather than filing a retaliatory suit in district court, which can take years to run its course.

The ITC's recently proposed rule amendments that require all nongovernmental parties in Section 337 investigations to disclose information about "entities that have an ownership or a financial interest in the investigation," including the identities of any litigation funders, may also affect who participates in future investigations, as not all parties may be willing to disclose this information.[27]

In any event, smaller companies should recognize that the ITC may now be more accessible to them and consider how to use the ITC to strategically enforce or defend against a claim.

Evaluate all public interest issues and arguments before filing a complaint — do not underestimate how these issues could weigh against a possible remedy or result in exemptions to any remedy.

The commission may alter or deny its remedy based on public interest concerns.

However, it has completely denied relief only three times, and in each instance, a short supply or

shortage adversely affecting public health or welfare was key to the analysis.[28]

For life sciences companies, public interest concerns are especially important because the articles involved in these investigations can significantly affect public health or welfare; after all, the classic tug-of-war here is between enforcing IP rights and safeguarding public health.

Complainants should know that the commission may delegate public interest to the presiding administrative law judge, so these issues need to be addressed in the parties' filings during the investigative phase.[29] Even if a remedy will not adversely affect the public health or welfare, delegation of a public interest issue to an ALJ most likely will increase the litigation costs in the investigation.

In addition, complainants should know that even if a violation is found, the ITC may deny or tailor the remedy because of public interest concerns.

For example, in Certain Microfluidic Devices in 2020, the commission tailored the limited exclusion order to allow infringing devices to be "imported ... for use by researchers ... who have a documented need to continue receiving the devices for a specific current ongoing research project for which that need cannot be met by any alternative product."[30]

The commission did so because "the evidence show[ed] that switching from the GEM Chips to the Next GEM Chip or another technology mid-study would disrupt important medical research, result in research studies that have questionable conclusions, and result in loss of data and wasted time, money, and effort."[31]

More recently, in Certain Cochlear Implant Systems and Components Thereof last year, the private parties settled on the eve of trial, but the staff attorney's pretrial brief observed that "the evidence will support a recommendation that the public interest factors weigh against the issuance of an exclusion order."[32]

This case suggests that, although denial of a remedial order may be rare, the threat of denial still has teeth, and due to the inherent tension between the parties, there may be a rise in public interest disputes during the investigation that result in denials or tailored remedial orders.

Because public interest concerns can affect the remedial orders, private parties should fully develop their arguments before an investigation is instituted, and always assess whether and how to solicit and use comments from third parties as needed to bolster the record in their favor.

Conclusion

The ITC is a powerful forum that may soon become a significant battleground for life sciences companies as global IP and trade disputes continue.[33]

As the intersection between IP and trade in the life sciences industry becomes increasingly more important, life sciences companies should stay on top of the developments discussed above and consider how they can use the ITC as part of their litigation strategies to target their global competitors and gain the highest market advantage.

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[1] 19 U.S.C. § 1337.

[2] 19 U.S.C. § 1337(d). There are two types of exclusion orders: limited exclusion orders and general exclusion orders.

[3]U.S. Int'l Trade Comm'n, Section 337 Statistics: Number Cases in Which Violation is Found/Yr (last updated February 3, 2026), available at https://www.usitc.gov/intellectual_property/337_statistics_number_cases_which_violation.htm.

[4] U.S. Int'l Trade Comm'n, Section 337 Statistics: Technology Areas of Accused Products (% Over the Years) (last accessed May 27, 2026), available at https://www.usitc.gov/intellectual_property/337_statistics_types_accused_products_new_filings.htm.

[5] Amarin Pharma, Inc. v. Int'l Trade Comm'n, 923 F.3d 959, 961-62, 969 (Fed. Cir. 2019).

[6] Id. at 969.

[7] Certain Products Containing Tirzepatide and Products Purporting to Contain Tirzepatide ("337-TA-1377"), Inv. No. 337 TA-1377, Complaint at 17-23 (Oct. 19, 2023) (Doc. ID 806421).

[8] Id. at 25-26; see also 337-TA-1377, Public Interest Comments from the U.S. Food and Drug Administration at 2-3 (Nov. 8, 2023) (Doc. ID 808120) (observing that Eli Lilly's "Complaint does not appear to be an attempt by a private party to enforce the FDCA").

[9] Amarin, 923 F.3d at 961.

[10] Amgen Inc. v. Int'l Trade Comm'n, 565 F.3d 846, 848-49 (Fed. Cir. 2009). In Edwards Lifesciences Corp. v. Meril Life Scis. Pvt. Ltd., the Federal Circuit explained that "for each act of infringement the safe harbor is available only for acts or uses that bear a reasonable relation to the development and submission of information to the FDA." 96 F.4th 1347, 1353 (Fed. Cir. 2024).

[11] Certain Drug Products Containing C-Type Natriuretic Peptide Variants, and Components Thereof ("337-TA-1447"), Inv. No. 337-TA-1447, Complaint at 13, ¶ 48 (April 1, 2025) (Doc. ID 847560).

[12] Id. at 13, ¶ 48. BioMarin later added Bachem AG as a named respondent in this investigation. 337-TA-1447, Amended Complaint at 8-9, ¶¶ 26-28 (Aug. 22, 2025) (Doc. ID 860269).

[13] See 337-TA-1447, Ascendis Proposed Respondents' Statement Regarding Non-Institution of Investigation or, Alternatively, Requesting Invocation of the 100-Day Program (April 16, 2025) (Doc. ID 848888); 337-TA-1447, Proposed Respondent Wacker's Wacker request for non-institution or placement of the investigation into the 100-day program (April 16, 2025) (Doc. ID 848906).

[14] 337-TA-1447, Institution of Investigation (May 2, 2025) (Doc. ID 850271); Order Denying Requests for Entry into Early Disposition Program at 1 (May 2, 2025) (Doc. ID 850273).

[15] Ascendis Pharma A/S v. BioMarin Pharm. Inc., 170 F.4th 1368, 1372-73 (Fed. Cir. 2026).

[16] Id. at 1373.

[17] Id.

[18] Id. at 1371, 1373, 1377-79.

[19] See Ascendis Pharma A/S et al v. Biomarin Pharm. Inc., 4:25-cv-05696, Dkt. No. 75 (March 18, 2026).

[20] Ascendis, 4:25-cv-05696, Dkt. No. 82 at 3 (March 30, 2026).

[21] See 337-TA-1447, Staff's Initial Post-Hearing Brief at 24, 136 (May 21, 2026) (Doc. ID 882914). One other respondent maintains this defense. Id. at 24.

[22] Certain Pertuzumab Biosimilars, Including Those Made by Certain Methods of Manufacturing, the Active Ingredient Thereof, and Products Containing the Same ("337-TA-3890), Inv. No. 337-TA-3890, Proposed Respondents Request for No Institution or, in the Alternative, Request for Early Disposition under 19 CFR 210.10(b)(3) at 4 (Mar. 12, 2026) (Doc. ID 875344).

[23] 337-TA-3890, Complainant's Third Request for Extension of Institution Deadline at 1 (May 15, 2026) (Doc. ID 882367); see also 337-TA-3890, Voting Sheet at 1 (May 21, 2026) (Doc. ID 882903); 337-TA-3890, Complainant's Fourth Request for Extension of Institution Deadline at 1 (June 8, 2026) (Doc. ID 884518).

[24] Lashify, Inc. v. Int'l Trade Comm'n, 130 F.4th 948, 963 (Fed. Cir. 2025), amended, No. 2023-1245, 2026 WL 293128 (Fed. Cir. Feb. 4, 2026).

[25] Wuhan Healthgen Biotechnology Corp. v. Int'l Trade Comm'n, 127 F.4th 1334, 1339 (Fed. Cir. 2025).

[26] 91 Fed. Reg. 26989 (May 13, 2026).

[27] 91 Fed. Reg. 23190 (April 30, 2026). Comments on these proposed amendments are due by June 29, 2026.

[28] Spansion, Inc. v. Int'l Trade Comm'n, 629 F.3d 1331, 1360 (Fed. Cir. 2010).

[29] In 2025, the ITC delegated public interest to the ALJ "in about 27 percent of total new investigations." U.S. Int'l Trade Comm'n, Section 337 Statistics: Investigations Delegating Public Interest (last updated Feb. 3, 2026), available

at https://www.usitc.gov/337_stats_delegating_public_interest (emphasis omitted); see, e.g., Certain Antibody Drug Conjugates and Components Thereof, and Products Containing the Same, Inv No. 337-TA-1466, Notice of Institution at 2 (Dec. 17, 2025) (Doc. ID 866810).

[30] Certain Microfluidic Devices, Inv. No. 337-TA-1068, Comm'n Op. at 1, 22-48, 53-54 (Jan. 10, 2020) (Doc. ID 698855).

[31] Id. at 45.

[32] Certain Cochlear Implant Systems and Components Thereof ("337-TA-1418"), Inv. No. 337-TA-1418, Staff's Pre-Hearing Brief at 202-23 (May 28, 2025) (Doc. ID 852197); see also 337-TA-1418, Joint Motion to Terminate the Investigation on the Basis of Settlement (May 30, 2025) (Doc. ID 852410).

[33] The ITC recently self-instituted an investigation "to produce a report as directed by the U.S. Senate Committee on Appropriations reviewing the extent to which Chinese state support and pricing practices in the biotechnology sector may be affecting market share and competitiveness of the U.S. industry." 91 Fed. Reg. 10154 (Mar. 2, 2026). The anticipated publication date of the report is January 22, 2027. Impact on U.S. Industry of China's State Support and Pricing Practices in the Biotechnology Sector, Inv. No. 332-TA-610, Notice of Investigation and Scheduling of a Public Hearing at 1 (Feb. 26, 2026) (Doc. ID 873717).