

ITC 100-Day Early Disposition: Little Used But Top Of Mind

By **Mary Prendergast and Myles Young** (March 1, 2023, 2:39 PM EST)

The U.S. International Trade Commission recently instituted an investigation in Certain Selective Thyroid Receptor-Beta Agonists, a trade secrets case involving treatments for certain liver ailments.

The Feb. 3 ITC notice included a surprise. The commission ordered the administrative law judge, or ALJ, to decide, within 100 days, whether the complainant meets the statutory requirement of an injury to domestic industry.[1]

This is the first time the ITC has ordered a 100-day proceeding on this issue in a trade secrets context. The ITC's decision to do so sua sponte may signal a renewed focus on resolving ITC investigations early and avoiding unnecessary expenditure of time and expense for parties and the commission.

Early Resolution in the ITC

The ITC provides a powerful tool for intellectual property owners. Investigations move quickly and the commission can issue injunctive-type relief by excluding imports of infringing products.

For respondents, the ITC is an expensive proposition due to the speed of proceedings and the broad scope of discovery.

For respondents who find themselves defending an ITC action, the first question often is, "How can I get out of this quickly?" In recent years, the ITC has created two programs allowing administrative law judges to issue early rulings on potentially dispositive issues, which could avoid the need for a full hearing and commission review.

The ITC's 100-Day Program: Little Used and Even Less Effective

The ITC launched the first of these programs, the 100-day pilot program, in 2013.[2] Its goal was to reduce costs associated with the litigation of specific issues such as domestic industry, importation and standing. The commission felt these dispositive issues were often determined only after a year or more of expensive litigation.[3]

After a complaint is filed, a respondent may ask the ITC to institute a 100-day proceeding. If the



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commission agrees, the ALJ is required to expedite fact finding on the issue, hold an early evidentiary hearing and make an initial determination within 100 days.

A decade after the program began, 100-day proceedings remain rare. To date, the program has been used to determine:

- Whether the economic prong of the domestic industry requirement was met: nine times;
- Whether the complainant meets the statutory requirement of an injury to domestic industry: once;[4]
- Whether the subject invention was patentable under Title 35 of the U.S. Code, Section 101: once;[5]
- Whether the complainant was precluded from bringing their case before the ITC: once;[6]
- Whether the complainant was contractually barred from claiming patent infringement: once;[7] and
- Whether the complainant had standing — once.[8]

In total, respondents have been successful in obtaining a case-dispositive 100-day ruling only twice, but the program has led to resolution before the hearing in several other investigations.[9]

In eight of these investigations, the parties either settled or the complaint was withdrawn before the ALJ could even rule on the 100-day issue. In three others, the ALJ issued a decision and the parties settled shortly thereafter.[10]

The best way to succeed on a 100-day request is to present a straightforward issue requiring little-to-no discovery. Otherwise, the commission may find the issues too complex or fact-intensive to determine within 100 days.

For example, the commission has denied a 100-day request on domestic industry because it foresaw the likely necessity of third-party discovery.[11]

And in an investigation alleging theft, conversion, and trade secret misappropriation, the commission declined to grant 100-day requests on statute of limitations and preemption defenses, deeming them too complex.[12]

The commission may also deny requests where not all issues would be disposed of by the 100-day ruling.

In a 2019 decision in *Certain Data Transmission Devices, Components Thereof, Associated Software, and Products Containing the Same*, the commission denied a request to determine subject matter eligibility, finding the issues were unlikely "to be dispositive with respect to all (and not just some) of the asserted claims of the Asserted Patents." [13]

In cases where it has granted a 100-day request, the commission has sometimes done so because of a procedural anomaly.

In a 2019 decision in Dissolving Microneedle Patch Technology for Cosmetic and Pharmaceutical use, for example, the complaint was unclear, making it difficult to determine whether the economic or technical prongs of the domestic industry requirement were satisfied.

The ITC granted a 100-day request on the economic prong without comment.[14]

In a 2016 decision in Certain Silicon-on-Insulator Wafers, the complainant initiated its second investigation against the same respondent a mere eight days after it had withdrawn its previous complaint. In the previous investigation, the ALJ had granted a motion striking any late-produced evidence on domestic industry.

Unable to establish domestic industry, the complainant withdrew its complaint and refiled. Given the previous lack of evidence, the commission granted a 100-day proceeding on the economic prong of the domestic industry requirement.[15]

The Commission's Voluntary Use of the 100-Day Program

In view of the history of the 100-day program, the commission's decision in Certain Selective Thyroid Receptor-Beta Agonists is notable.

On Dec. 29, 2022, Viking Therapeutics Inc. filed a complaint alleging that the respondents Ascleptis BioScience Co. Ltd., its affiliates and Jinzi Wu import products that use Viking's trade secrets.

Viking alleged that the accused products are expected to be used for therapeutic purposes and that the respondents plan to eventually commercialize the accused products within the U.S.

Although they filed comments on the public interest, the respondents did not ask the commission to institute a 100-day proceeding.

The respondents did, however, comment that an investigation "would harm the public interest by depriving consumers of the opportunity to access currently non-existent therapies for serious health conditions and forcing customers to pay much higher prices." [16]

Ostensibly in response to disagreement between the parties on the issue of whether a domestic market exists, the commission ordered the presiding ALJ to determine, under the 100-day program,

whether complainant can show that the threat or effect of the alleged unfair acts is to (i) to destroy or substantially injure an industry in the United States, or (ii) to prevent the establishment of such an industry.[17]

Commissioner Rhonda K. Schmidlein dissented, noting that she would not have granted a 100-day proceeding.[18]

Schmidlein explained:

[N]either the complainant nor any proposed (or now named) respondent has requested a 100-day proceeding in this investigation or asserted that such an expedited proceeding will result in any efficiencies, such as limiting unnecessary litigation, or saving time and costs for the parties.

Although noting the commission's ability to order 100-day treatment voluntarily, Schmidtlein viewed the issues as too complex for resolution within 100 days.

Given that the commission is often reluctant to order 100-day IDs even in cases where both parties request them, it is particularly notable that the commission initiated this ID voluntarily.

Commissioner Schmidtlein's dissent, however, suggests this may not be a regular occurrence.

The ITC's Interim ID Program: A Second Path to Early Resolution

On May 12, 2021, the ITC initiated a second pilot program empowering ALJs to issue interim IDs on specific issues instead of requiring a go-ahead from the commission.[19]

The program gives ALJs discretion to consider, either at the parties' request or voluntarily, case-dispositive or otherwise significant issues that may facilitate settlement. Parties may seek interim IDs under this program after trying, but failing, to get 100-day treatment from the commission.

Chief ALJ Clark S. Cheney has been the only ALJ to use this pilot program thus far. In February 2022, he announced that he would review the issue of domestic industry on an interim basis in two related investigations.[20]

This did not lead to an early resolution, however, as Judge Cheney issued interim IDs finding the economic prong was met in July 2022. The investigations remain ongoing.[21]

In May, the commission will review the program's usage and decide whether to permanently allow and issue rules regarding interim IDs. If it follows the path of the earlier 100-day pilot program, the second pilot program will become permanent. Early resolution, however, may remain hard to come by for ITC respondents.

Takeaways

Despite the ITC's historically limited use of the 100-day program, it is still an option that apparently remains very much on the minds of the ITC commissioners.

Respondents should continue to consider filing 100-day requests on relatively straightforward issues, since their grant may create significant settlement leverage.

Even if a request is denied, the respondent will have previewed the issue for the ALJ and could potentially seek an interim ID or move for summary determination before the hearing.

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[1] Certain Selective Thyroid Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same,

and Products Containing Same ("Certain Selective Thyroid Receptor-Beta Agonists"), Inv. No. 337-TA-1352, Not. of Institution (Feb. 3, 2023).

[2] The ITC made this program permanent effective June 7, 2018, via integration into the ITC rules. See 83 Fed. Reg. 21140 (May 8, 2018) (codified at 19 C.F.R. §§ 201, 210).

[3] https://www.usitc.gov/press_room/featured_news/pilot_program_will_test_early_disposition_certain.htm.

[4] Unlike Certain Selective Thyroid Receptor-Beta Agonists, the case alleged false advertising and unfair competition under the Lanham Act. Certain Clidinium Bromide and Products Containing Same, Inv. No. 337-TA-1109, Not. of Institution (Apr. 18, 2018).

[5] Certain Portable Electronic Devices and Components Thereof ("Certain Portable Electronic Devices"), Inv. No. 337-TA-994, Not. of Institution (May 5, 2016).

[6] Certain Integrated Circuits and Products Containing the Same, Inv. No. 337-TA-1246, Not. of Institution (Feb. 8, 2021).

[7] Certain Motorized Vehicles and Components Thereof, Inv. No. 337-TA-1132, Not. of Institution (Sept. 7, 2018).

[8] Certain Audio Processing Hardware and Software and Products Containing the Same, Inv. No. 337-TA-949, Not. of Institution (Mar. 12, 2015).

[9] Certain Portable Electronic Devices, Comm'n Determination; Term. of Investigation (Sept. 20, 2016); Certain Products Having Laminated Packaging, Laminated Packaging, and Components Thereof, Inv. No. 337-TA-874, Comm'n Op. (Sept. 3, 2013) (finding lack of economic domestic industry in expedited proceeding).

[10] Certain Silicon-on-Insulator Wafers, Inv. No. 337-TA-1025, Comm'n Determination (Mar. 10, 2017); Certain Audio Processing Hardware and Software and Products Containing the Same, Inv. No. 337-TA-949, ID (Jul. 15, 2015); Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same, 337-TA-1097, Comm'n Determination (June 20, 2019).

[11] See, e.g., Certain Video Processing Devices, Components Thereof, and Digital Smart Televisions Containing the Same, Inv. No. 337-TA-1222, Order (Oct. 14, 2020).

[12] See, e.g., Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same, Inv. No. 337-TA-1313, Order (May 2, 2022).

[13] Certain Data Transmission Devices, Components Thereof, Associated Software, and Products Containing the Same, Inv. No. 337-TA-1150, Order (Apr. 2, 2019).

[14] Certain Dissolving Microneedle Patch Technology for Cosmetic and Pharmaceutical Use, Inv. No. 337-TA-1189, Not. of Institution (Jan. 10, 2020).

[15] Certain Silicon-on-Insulator Wafers, Inv. No. 337-TA-1025, Not. of Institution (Oct. 19, 2016).

[16] Certain Selective Thyroid Receptor-Beta Agonists, Comments on Public Interest by Proposed Respondents (Jan. 12, 2023).

[17] The case illustrates the extremely expedited and punishing nature of a 100-day proceeding. Under the recently proposed procedural schedule, discovery closes March 13, a two-day evidentiary hearing is scheduled for March 29 — 30, post-hearing briefs are due April 14, and the ID is due May 22.

[18] Certain Selective Thyroid Receptor-Beta Agonists, Institution of Investigation (Feb. 3, 2023) (Commissioner Schmidlein, dissenting).

[19] https://www.usitc.gov/press_room/featured_news/337pilotprogram.htm.

[20] Certain Replacement Automotive Lamps, Inv. No. 337-TA-1291; Certain Replacement Automotive Lamps, Inv. No. 337-TA-1292, Order (Jan. 25, 2022).

[21] Certain Replacement Automotive Lamps, Inv. No. 337-TA-1291; Certain Replacement Automotive Lamps, Inv. No. 337-TA-1292, Interim ID (July 1, 2022).