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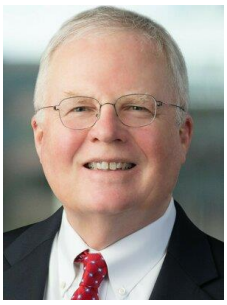
What Case Trends Reveal About Life Sciences Results At ITC

By **Brian Busey and Daniel Muino** (October 16, 2023, 5:26 PM EDT)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For many years, U.S. International Trade Commission Investigations under the Section 337 exclusion order have predominantly involved computer technology, telecommunications technology and consumer electronics.

Over the last decade, however, there have been a growing number of cases involving pharmaceuticals, medical devices and other life sciences technologies under Section 337 — which directs customs to stop infringing imports from entering the country.

This article highlights recent trends in life sciences cases at the ITC and examines how the ITC has approached the economic domestic industry requirement and the statutory public interest factors — especially the public health and welfare — in life sciences cases.

Increasing Share of Section 337 Investigations Involve Life Sciences Technologies

During the last five fiscal years, 2018 to 2023, 39 out of 276 Section 337 investigations have involved life sciences technologies, including pharmaceuticals, medical devices and medical supplies.[1]

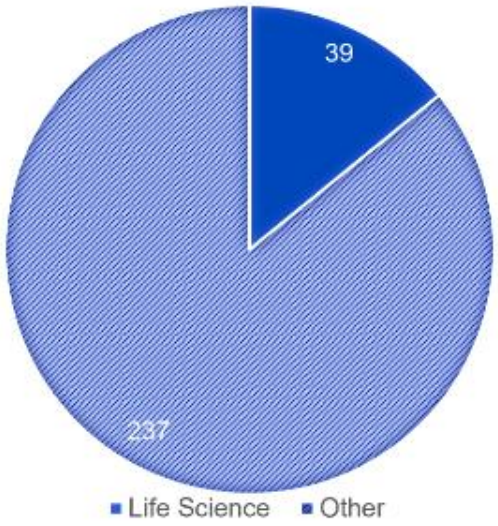
This amounts to 14% of ITC Section 337 investigations in this period. For perspective, this represents an increase from only 29 life sciences cases in the seven fiscal years from 2011 to 2017.

These investigations have covered a broad range of life sciences technologies, for example, a drug for treating stomach ulcers,[2] computer-assisted medical devices that generate and infuse pharmaceuticals into a patient to generate images of organs,[3] and growth supplements for cell cultures used in vaccine development.[4]

Additional technologies have included skin rejuvenation resurfacing devices[5] and tourniquets for restricting blood flow.[6]

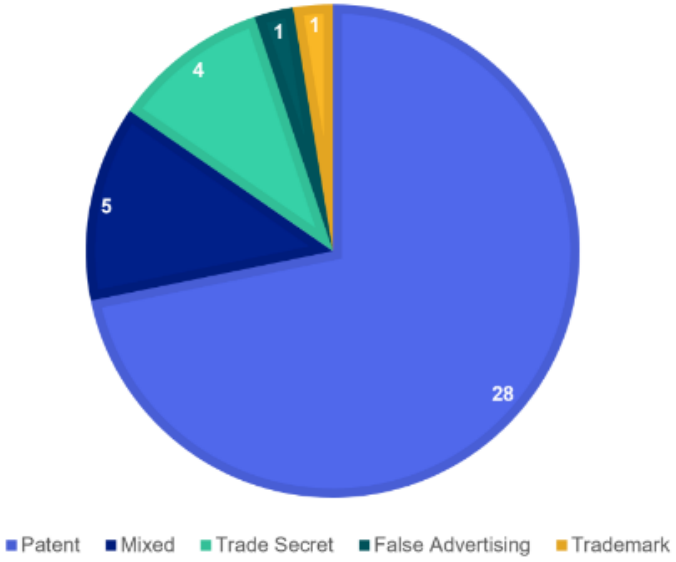
As with all Section 337 investigations, most life sciences cases involve assertions of patent rights. Of the 39 life sciences investigations during the five-year period from 2018 to 2023, 28 involved claims of patent infringement. Other unfair acts asserted in these cases included trade secret misappropriation (4), false advertising (1), trademark infringement (1), and a combination of unfair acts (5).

Life Sciences Make Up a Growing Portion of ITC Section 337 Investigations

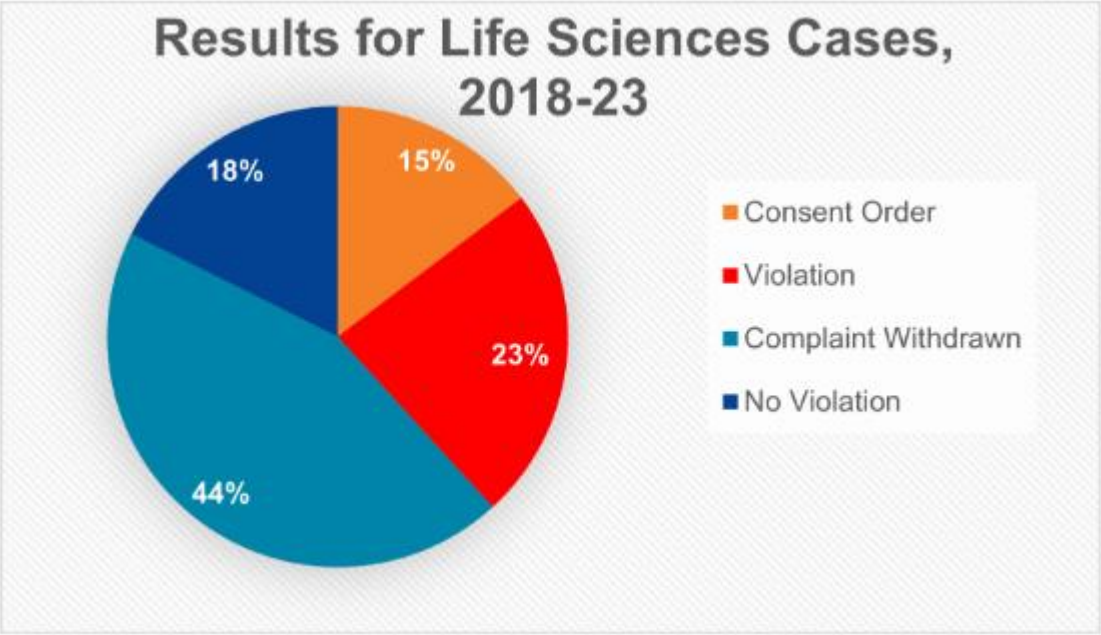


Variety of IP Rights Asserted Before the ITC in Life Sciences Cases

- Multiple patents or forms of IP may be at issue in a single investigation



The majority of life sciences cases at the ITC have generated positive results for the complainant IP rights-holders. A snapshot of the results in the 39 life sciences cases from fiscal years 2018 to 2023 is shown below.



As the data shows, 23% of the cases resulted in a determination of violation of Section 337, meaning that the complainant's IP rights were found to be infringed by the imported accused products and ITC remedial orders blocking importation were imposed.

Another 15% resulted in ITC consent orders for at least some respondents under which they were prohibited from importing infringing products and agreed to the continued jurisdiction of the ITC over enforcement of such orders. Thus, 38% of the cases resulted in ITC orders granting relief to the complainant. Further, another 44% of the investigations were terminated based on withdrawal of the complaint, which typically means that the parties have reached a settlement agreement.

During this five-year period, the ITC found no violation of Section 337 in only 18% of the life sciences cases.

Navigating the Economic Domestic Industry Requirement

Pursuant to the economic prong of the ITC's domestic industry requirement, the complainant must demonstrate that they, or their licensees, have made significant U.S. domestic investments in connection with articles that practice the asserted patents or other IP.

This is shown by evidence of significant domestic investment in plant, equipment, capital, or labor relating to the practicing articles — e.g., product manufacturing or development — or substantial investment in engineering, research and development, or licensing relating to the asserted patents or other IP.

Complainants in life sciences cases have relied on a broad variety of activities to satisfy the domestic industry requirement.

For example, the 2019 Certain Strontium-Rubidiuma decision involved a medical device company that relied on salaries paid to U.S. engineers working on the practicing domestic industry device, as well as expenses for services to design and develop the device.[7]

Meanwhile, the October 2022 Certain Plant-Derived Recombinant decision involved another life sciences complainant that developed a genetically engineered, plant-based protein production system that relies on the life cycle of rice to produce recombinant proteins, or rHSA, used in the manufacture of medicines and vaccines.

This complainant relied on, among other things, its investment in farmland where proprietary rice was cultivated, as well as the labor costs of U.S. employees engaged in research and development, laboratory work, rice breeding, and manufacturing of rHSA.[8]

In addition, the 2021 Certain In Vitro Fertilization Products, Components Thereof, and Products Containing the Same decision involved a case in which the complainant relied in part on expenses of educating "health care providers on the science of fertility drugs."[9]

A key issue in life sciences cases where the products are subject to U.S. Food and Drug Administration approval is whether preapproval of research and development expenses can be counted for economic domestic industry purposes.

Based on several recent decisions, such preapproval expenses can be counted toward domestic industry. In Strontium, the ITC held that salaries for employees supporting the FDA regulatory approval activities were properly included even if there was not yet an FDA-approved medical device.[10]

The ITC subsequently affirmed this view in a case involving tobacco vaping devices, the 2021 Certain Tobacco Heating Articles and Components Thereof decision.[11]

Most recently, in the March 2023 Philip Morris Products S.A. v. ITC ruling, the U.S. Court of Appeals for the Federal Circuit affirmed that the commission may count investments in domestic industry articles even if they have not been approved by the FDA.[12]

In reviewing Section 337's domestic industry requirement, the court held that "[n]othing in the plain language of the statute requires that the protected [domestic] articles have regulatory approval."[13]

Public Interest Considerations in Life Sciences Cases

One area of potential special concern in life sciences cases is the public interest requirement. Section 337 requires the ITC, upon finding a violation of the statute, to issue an exclusion order barring importation of the infringing articles

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds such articles should not be excluded from entry.[14]

The commission considers the same public interest factors before issuing the alternative relief of a cease and desist order.[15]

While it rarely does so, the ITC may determine that no remedial orders should issue — despite all other requirements being met — because of adverse impacts on the public interest.

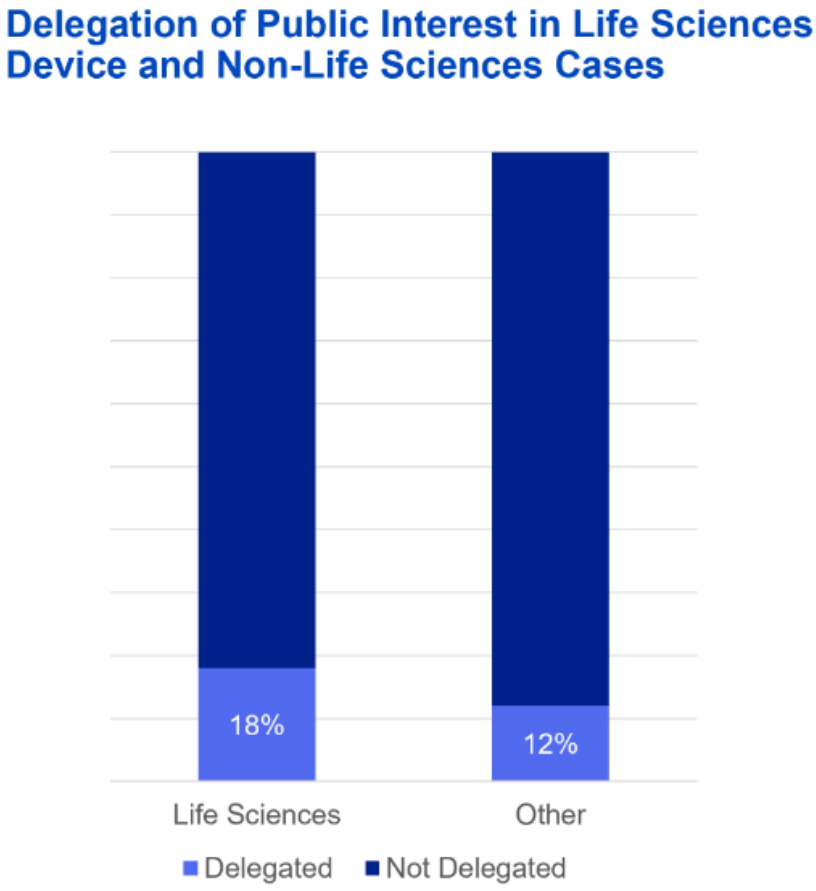
For instance, in the older, 1984 Certain Fluidized Supporting Apparatus and Components Thereof decision, involving specialized hospital beds used to treat burn victims, the ITC denied the complainant's requested remedial orders due to public interest concerns as to whether a sufficient supply of such specialized beds would remain available.[16]

It is worth noting that the ITC has only denied remedial orders in three investigations — including the hospital bed case — and has not done so since 1984. In other cases, the ITC has tailored the remedial orders in light of public interest factors; for example, delaying the implementation of remedial orders to allow time for substitute products to be supplied.

More recently in the 2020 Certain Microfluidic Devices decision, the ITC tailored relief to allow continued importation of infringing chips used for ongoing medical research into cancer and cardiovascular treatments to minimize the impact on public health and welfare.[17]

Life sciences technologies may, in theory, implicate public interest concerns, particularly public health and welfare, more often than other technologies — e.g., mobile devices or consumer electronics.

One measure of this is how frequently the ITC delegates the public interest issues to the administrative law judges for discovery and fact-finding. From 2018 to 2023, public interest was delegated to the ALJs in approximately 12% of cases not involving life sciences, but 18% of life sciences cases.



These statistics and the ITC's recent decisions in life sciences cases suggest that, while there is some

heightened sensitivity to public interest factors in such cases, it rarely results in alterations to the remedial orders.

In one recent example, the 2021 Certain Tobacco Heating Articles and Components Thereof, the commission rejected Philip Morris's arguments that its electronic tobacco heating devices should continue to be imported as they were a healthier alternative to combustible cigarettes.[18]

The commission noted that there were many other FDA-approved therapies to reduce use of cigarettes and therefore exclusion of Philip Morris's products would not affect public health and welfare.[19]

This case is to be contrasted the 2020 Certain Microfluidic Devices decision, another life science case where the ITC tailored relief to allow continued importation of devices necessary for ongoing cancer and cardiovascular research where it was impractical in the short term to switch to alternative products.[20]

Conclusion

Recent data shows pharmaceuticals, medical devices and other life sciences products constitute a growing share of the technologies involved in Section 337 investigations. Life sciences companies that are facing competition from imported infringing products should consider the ITC as a forum for enforcing their IP rights.

Although life sciences companies should be mindful of the special considerations they may face with respect to Section 337's domestic industry requirement and statutory public interest factors, these issues do not appear to create significantly higher hurdles to success at the ITC than for firms in nonlife sciences industries.

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[1] Data examined through July 2023.

[2] Certain Clidinium Bromide and Products Containing Same, Inv. No. 337-TA-1109 (2018).

[3] Certain Strontium-Rubidium Radioisotope Infusion Systems, and Components Thereof Including Generators, Inv. No. 337-TA-1110 (2018).

[4] Certain Plant-Derived Recombinant Human Serum Albumins ("rHSA") and Products Containing Same, Inv. No. 337-TA-1238 (2021).

[5] Certain Skin Rejuvenation Resurfacing Devices, Components Thereof, and Products Containing the Same, Inv. No. 337-TA-1262 (2021).

[6] Certain Blood Flow Restriction Devices with Rotatable Windlasses and Components Thereof, Inv. No. 337-TA-1364 (2023).

[7] Certain Strontium-Rubidium, Inv. No. 337-TA-1110, , Comm'n Op. at 40-42 (Dec. 11, 2019).

[8] Certain Plant-Derived Recombinant, Inv. No. 337-TA-1238, Initial Determination at 2, 102-03 (April 7, 2022), rev'd and aff'd in part, Comm'n Op. at 52-53 (Oct. 11, 2022).

[9] Certain In Vitro Fertilization Products, Components Thereof, and Products Containing the Same, Inv. No. 337-TA-1196, Comm'n Op. at 18-19 (Oct. 28, 2021) (vacating and remanding in part).

[10] Certain Strontium-Rubidium, Inv. No. 337-TA-1110, , Comm'n Op. at 40-42 (Dec. 11, 2019).

[11] Certain Tobacco Heating Articles and Components Thereof, Inv. No. 337-TA-1199 (2021).

[12] Philip Morris Prod. S.A. v. Int'l Trade Comm'n, 63 F.4th 1328, 1341 (Fed. Cir. 2023).

[13] Id.

[14] 19. U.S.C. § 1337(d)(1).

[15] 19. U.S.C. § 1337(f)(1).

[16] Certain Fluidized Supporting Apparatus and Components Thereof, Inv. Nos. 337-TA-182/188, USITC Pub 1667, Comm'n Op. at 1-2, 23-25 (Oct. 5, 1984).

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

[18] Certain Tobacco Heating Articles and Components Thereof, Inv. No. 337-TA-1199, Comm'n Op. at 60-62 (Oct. 19, 2021).

[19] Id. at 60.

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