

ITC Decision Shows Importance Of Public Interest For Biotech

By **Matt Rizzolo and Rachael Bacha** (January 21, 2020)

The U.S. International Trade Commission has become a popular venue for patent infringement actions, as it provides for fast and powerful exclusionary remedies against infringers in the form of exclusion and cease-and-desist orders, through which the ITC can bar importation of infringing products into the United States.

Importantly, the ITC does not apply the equitable eBay factors before issuing such relief. Instead, it must consider the so-called public interest factors: the effect of the orders upon (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) the production of like or directly competitive articles in the U.S., and (4) U.S. consumers.

A recent ruling from the ITC shows that while they seldom affect whether and to what extent the ITC issues a remedy, the ITC's public interest factors can be a valuable tool for respondents and third parties to limit the scope of a remedy even in the face of an infringement finding. This is particularly true where the ITC's remedy has the potential to adversely affect the public health and welfare.

This past December, the ITC issued a limited exclusion order in Certain Microfluidic Devices, in which products otherwise covered by the order would be exempted if they are "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."^[1]

In short, the ITC evaluated the public interest factors and determined that the public interest would be best served if certain qualifying — though infringing — devices were allowed to continue entering the U.S. This ruling highlights the importance the public interest factors can sometimes play in an ITC investigation, especially in the biotechnology context.

The ITC's Public Interest Factors

The ITC's statute provides:

If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the [public interest factors], it finds that such articles should not be excluded from entry.^[2]

While much of a Section 337 investigation proceeds before an administrative law judge, for decades, the public interest factors were evaluated only by the commission, after the ALJ had made his or her initial determination on the merits of the complainant's Section 337 claims. But in order to better develop the factual record for public interest considerations, since 2010 the ITC has chosen to delegate public interest-related discovery and an initial recommendation on public interest to the ALJs in over 100 investigations.



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Whoever considers the public interest factors — the ALJ, the ITC or both — the inquiry is the same: Evaluate the impact that an exclusion order would have upon (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) the production of like or directly competitive articles in the U.S., and (4) U.S. consumers.

Because the ITC has repeatedly held that there is a very strong interest in enforcing intellectual property rights, the public interest inquiry does not affect the remedy in the vast majority of investigations. But based on the presence of significant public interest concerns, the ITC has, in the past, seen fit to sometimes issue tailored remedies[3] and in very rare cases even deny relief altogether.[4]

The Microfluidic Devices Investigation, Remedy and Decision

The ITC's recent decision in Certain Microfluidic Devices stems from a complaint filed in September 2017 by Bio-Rad Laboratories Inc. and Lawrence Livermore National Security LLC against 10X Genomics Inc., alleging 10X of infringing several patents relating to microfluidic devices used in a wide variety of laboratory applications. In this case, the ITC delegated public interest discovery to the ALJ.

In September 2018, the ALJ issued an initial determination finding a violation of Section 337 based on infringement of three asserted patents and issued a recommended determination finding that the public interest did not require tailoring of any exclusionary relief. As is common in ITC investigations, the ITC chose to review the ALJ's ID and also asked for submissions from the public on public interest issues.

But over six months after it chose to review the ID, the commission took the unusual step of soliciting supplemental public interest submissions, both from the parties and the public, specifically directed to the effect the requested remedies would have on ongoing health-related research.

On Dec. 18, 2019, the commission issued a notice finding a violation of Section 337, as well as a limited exclusion order barring the importation of infringing 10X microfluidic devices and a cease and desist order prohibiting related domestic conduct. But in issuing this relief, the commission exempted from exclusion otherwise infringing products that were "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." [5]

Along with the limited exclusion order and cease and desist order the commission provided a questionnaire to be issued by 10X to researchers seeking to continue to use the subject products, asking them to certify the research being conducted, the period of use of the infringing products and whether and why alternative, noninfringing products could not be used.

On Jan. 10, the ITC issued the public version of its opinion in Certain Microfluidic Devices, explaining its reasoning for tailoring the exclusion order in this manner. The commission analyzed the public interest factors and the effect of any potential remedy on public health and welfare and found that a tailored remedy — in which certain infringing products were otherwise allowed to be imported and used in the U.S. — was appropriate.[6]

To be eligible for this carve-out from exclusion, though, researchers who had been using the infringing devices as of the date of issuance of the limited exclusion order were required to

provide respondents (and therefore, the U.S. government) with a documented need to continue receiving the devices for a specific current ongoing research project for which the researcher could not use an alternative, noninfringing product.[7]

In evaluating the effect of an exclusion order on the public health and welfare, the commission found that the basic scientific research being performed using the infringing devices, relating to, among other things, cancer and cardiovascular health, is “precisely the kind of activity intended by Congress to be included when it required the commission to consider the effect of a remedy on the public health and welfare.”[8]

As part of its analysis, the commission considered information provided by the parties and by researchers at a wide variety of institutions across the country, including Memorial Sloan Kettering Cancer Center, Harvard Medical School, Dana-Farber Cancer Institute Inc. and Stanford University School of Medicine.[9]

The commission determined that for certain ongoing research projects, it would be impractical or impossible for most researchers to switch to alternative, noninfringing products midstudy and that switching would potentially result in disruptions in important medical research, studies with questionable conclusions and loss of data, and wasted time, money, and effort.[10]

After analyzing the potential effects on the public health and welfare, the commission turned to the other public interest factors but found them to be largely “subsumed” by its significant concerns with respect to public health and welfare.[11]

In short, the commission in *Microfluidic Devices* determined that the impact of an exclusion order on the public interest — specifically, the public health and welfare as impacted by potential damage to scientific and medical research — necessitated a tailored remedy with an exemption for certain infringing products that are necessary for ongoing research purposes.

However, the commission did place additional burdens on 10X Genomics as the importer of such products — in addition to providing the researchers with questionnaires, the commission imposed a detailed reporting requirement on 10X Genomics, requiring it to provide, on a monthly basis, a detailed accounting of the devices being imported, the identity of the exempted customers, as well as the identity of the exempted research projects and their projected completion dates.

Takeaways

The ITC’s tailoring of its remedy in *Certain Microfluidic Devices* demonstrates the importance of the public interest factors and their potential impact on the scope of any available remedy — especially in the biotechnology or pharmaceutical context.

Although public interest concerns are typically insufficient to overcome the ITC’s interest in enforcing intellectual property rights, where overriding significant public interest issues do exist — such as where the products at issue are used in health care applications or for basic scientific or medical research — the ITC’s consideration of the public interest can make a significant difference in the form or scope of the remedy.

Potential ITC respondents should be armed to make their best arguments as to why public interest is an overriding concern in their particular case, while ITC complainants should be

aware of this potential hurdle and be ready to argue that, even if there are some public health and safety concerns, sufficient sources of alternative products exist.

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[1] Certain Microfluidic Devices, Inv. No. 337-TA-1068 (Jan. 10, 2020).

[2] 19 U.S.C. § 1337(d)(1).

[3] See, e.g., Certain Road Milling Machines & Components Thereof, Inv. No. 337-TA-1067, Comm'n Op. at 32-33 (July 18, 2019) (exempting service parts); Certain Baseband Processor Chips & Chipsets, Transmitter, & Receiver (Radio) Chips, Power Control Chips, & Prods. Containing Same, Including Cellular Tel. Handsets, 337-TA-543, USITC Pub. No. 4258, Comm'n Op. at 150-51 (Oct. 2011) (grandfathering certain products); Certain Personal Data & Mobile Commc'n Devices & Related Software, 337-TA-710, USITC Pub. No. 4331, Comm'n Op., at 72-73, 80-81 (June 2012) (delaying imposition of remedy).

[4] Certain Fluidized Supporting Apparatus and Components, Inv. No. 337-TA-182/188 (Oct. 1984) (declining relief because the accused beds were sold, rented and leased to hospitals for the treatment of burn patients); Certain Inclined Field Acceleration Tubes, Inv. No. 337-TA-67 (Dec. 1980) (declining relief because of likely effects on important scientific research) ("Acceleration Tubes"); and Certain Automatic Crankpin Grinders, Inv. No. 337-TA-60 (Dec. 1979) (declining relief due to countervailing national energy policies).

[5] LEO at 2-3 (emphasis added).

[6] Commission Opinion at 30-31.

[7] The Commission explained that such statements made by the researchers could be subject to criminally penalties if they were knowingly false. Microfluidic Devices, Comm'n Op. at 26 n.20.

[8] Microfluidic Devices, Comm'n Op. at 31, citing Acceleration Tubes, Comm'n Op. at 22.

[9] See Microfluidic Devices, Comm'n Op. at 31-34.

[10] Id. at 45.

[11] Id. at 48.