



Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

2023 ITC Section 337 Year in Review

Analysis & Trends

1ST EDITION

Sterne, Kessler, Goldstein & Fox is an intellectual property law firm of 200+ professionals devoted to providing outstanding patent and trademark legal services. Our services span the full range of IP services in the United States and globally, including litigation in all venues, patent and trademark prosecution, IP strategy, freedom-to-operate and other opinions, and transactional support.

For over 45 years, we have helped companies build and enforce worldwide IP portfolios. Sterne Kessler has a proven track record in the U.S. Patent and Trademark Office (USPTO), U.S. district courts, federal appeals courts, and the U.S. International Trade Commission (USITC). In the past five years, we have obtained more than 8,000 U.S. patents for our clients; we have led nearly 200 new district court cases in jurisdictions across the United States; we have more experience at the USITC than more than 85% of the firms appearing there; and we have handled nearly 400 new proceedings at the USPTO's Patent Trial and Appeal Board (PTAB).

Our appellate practice has deep experience that includes leading appeals of hundreds of PTAB final written decisions for some of the best-known technology and pharmaceutical companies in the world, in addition to numerous district court and USITC appeals. Our lawyers have clerked for Judges Bryson, O'Malley, Prost, Reyna, and Schall at the Federal Circuit, Judge Douglas H. Ginsburg at the DC Circuit, and Justice Kennedy at the Supreme Court.

Our investments in developing industry and technical expertise have enabled our lawyers to truly understand the business and strategies of companies in industries as diverse as electronic hardware and semiconductors, software solutions, biotechnology (therapeutic and industrial), pharmaceuticals, automotive technology, medical devices, mobile communications, sporting goods, and consumer products. We integrate technical, patent, and legal experience and knowledge in teams that can directly address our clients' needs.

Sterne Kessler's service model builds on the unrivaled technical depth of its professionals. Most have an advanced technical degree and significant industry or academic experience; more than 60 hold a Ph.D.; and well over 100 hold advanced technical degrees. Further, we have over a dozen former patent examiners on staff, strengthening our fundamental ability to obtain, defend, and enforce patents.

© 2024 Sterne, Kessler, Goldstein & Fox PLLC

The information contained in this publication is intended to convey general information only and should not be construed as a legal opinion or as legal advice. Sterne, Kessler, Goldstein & Fox PLLC disclaims liability for any errors or omissions, and information in this publication is not guaranteed to be complete, accurate, and updated. Please consult your own lawyer regarding any specific legal questions.

Introduction

Section 337 investigations at the ITC have proven to be an efficient and powerful method for Complainants seeking relief from unfair importation. The Commission's injunctive powers provide an attractive forum for Complainants seeking relief from patent infringement litigation and other unfair acts. In 2023, the number of complaints filed in federal courts was down over previous years, and the ITC was no exception. However, despite the lower number of investigations, the importance of the ITC remains strong as this year saw the resolution of two investigations against the Apple watch as well as other important products.

2023 also saw the resumption of in-person hearings at the ITC after the end of the COVID-19 procedures. The Commission appointed a new Administrative Law Judge, bringing the current total to six. The specter of government shutdowns loomed. But the ITC still continued its work, issuing 22 Final Determinations, of which 11 found a violation of Section 337.

In this inaugural issue of "The Year in Review," we will highlight some important legal decisions in 2023 involving the U.S. International Trade Commission, such as the recent Apple watch decision and the current standards for a cease-and-desist order in view of the fast-moving online marketplace. We will also review the success of design patents at the ITC and preview issues in the pending Automotive Lamp design patent cases filed by Kia and Hyundai. In addition, we will provide an update on some of the recent statistics as well as legislative proposals that are taking place globally with respect to the ITC.

The information provided in this review is the result of a collaborative process. Thank you to co-authors—Daniel Yonan, Paul Ainsworth, Josephine Kim, Ivy Estoesta, Davin Guinn, Brooke McLain, and Cristen Corry, as well as Nicholas Nowak, Jamie Dohopolski, and Patrick Murray, who contributed important data and statistics for this review.

We appreciate your interest in this report, and we encourage you to see our firm's other recently released publications "2023 Design Patents Year in Review: Analysis and Trends," "2023 PTAB Year in Review: Analysis & Trends," and "Federal Circuit IP Appeals: Summaries of Key 2023 Decisions," which are available at [sterneckessler.com](https://www.sterneckessler.com) or by request. Please contact us if you have questions about this report, wish to discuss questions about the ITC, and/or if you would like hard copies of any of our 2023 "year in review" reports.

Best regards,



Uma N. Everett

Director, Trial & Appellate Practice Group

Year-in-Review Webinars On Demand!



Access our four programs focused on the Federal Circuit, the Patent Trial and Appeal Board (PTAB), design patents, and the International Trade Commission. Panelists discuss summaries and analysis of key cases in each specialty area. View these webinars today!

Scan the QR code above to access Sterne Kessler's library of complimentary, on-demand webinars, including our 2023 IP Year-in-Review series.

Table of Contents

Introduction1

Editor and Author Biographies 4

Data and Trends: ITC Cases Instituted in 2023, Case Flow and Outcomes, and ITC Operations 16

Case Summaries

The Public Interest Impact – Considerations from *AliveCor* and *Masimo* 6

Looking Beyond Inventory Numbers to Secure a Cease and Desist Order 12

A Pair of Section 337 Investigations Involving Automotive Lamps
Illuminated the Potential of Design Patents 19

Rule and Procedural Developments at the ITC in 2023. 22

Editor and Author Biographies

Editors



Uma N. Everett is a director in Sterne Kessler's Trial & Appellate Practice Group. She tries patent cases before the United States International Trade Commission and in federal courts across the country. Uma is experienced in all aspects of litigation, from pre-suit investigation through trial and appeal. Uma has advised clients and litigated cases involving patents, trade secrets, contractual claims, as well as those involving a broad range of technologies, including pharmaceuticals, medical devices, LEDs, vehicle systems, telephone systems, communication systems, and consumer products.



Daniel E. Yonan is a director at Sterne Kessler and founded the firm's U.S. International Trade Commission (ITC) Practice Group. As lead counsel for both complainants and respondents, Daniel has taken multiple investigations through trial each year. Daniel's success and niche expertise in Section 337 law are based upon his knowledge of the Administrative Procedure Act as well as his early career training with a former Director of the Office of Unfair Import Investigations.



Paul A. Ainsworth is a director and first-chair trial lawyer in Sterne Kessler's Trial & Appellate Practice Group. His practice focuses his practice on patent and trade secret disputes in federal district courts, at the U.S. International Trade Commission, and before the U.S. Court of Appeals for the Federal Circuit. Paul also represents clients in administrative proceedings before U.S. Customs & Border Patrol involving the enforcement of ITC remedial orders.

Authors



Josephine Kim is a director in Sterne Kessler's Trial & Appellate Practice Group. She concentrates her practice in the area of patent litigation and has been involved in matters before federal district courts and the U.S. International Trade Commission. Josephine's intellectual property experience has been principally in technical areas such as pharmaceuticals, therapeutic methods, materials science, and mechanical arts. She has experience in all stages of litigation—initial fact investigation, claim construction, motions practice, expert discovery, and trial. Josephine has navigated complicated electronic discovery issues and is also experienced in case management of multi-defendant litigations.

Sterne Kessler is nationally and regionally ranked for excellence in patent litigation.

- U.S. News - Best Lawyers® "Best Law Firms 2024"



Ivy Clarice Estoesta is a director in Sterne Kessler’s Mechanical & Design Practice Group and Trademark & Brand Protection Practice. She counsels a wide variety of clients on the strategic procurement and enforcement of IP rights in the U.S. and globally, with a focus on design patents, trademarks, and copyrights. Ivy has niche expertise in U.S. and foreign design rights related to graphical user interface (GUI), augmented reality (AR), and virtual reality (VR) designs, and is the firm’s go-to resource for copyright matters, particularly for visual works, including digital art/NFTs, and works including AI-generated content. Ivy currently serves on the International Trademark Association’s Designs Committee and as the Complementary Forms of Design Protection Subcommittee Chair of the American Intellectual Property Law Association’s Industrial Designs Committee.



Nicholas J. Nowak is a trial lawyer and director in Sterne Kessler’s Trial & Appellate Practice Group. For over 20 years, he has focused on representing clients in complex patent and trademark matters in federal courts and in investigations before the U.S. International Trade Commission. Nick’s clients have included industry leaders in the pharmaceutical, medical device, automotive, electronics, and software industries. Nick’s practice also includes anti-counterfeiting and trademark enforcement as well as developing novel anti-counterfeiting solutions and strategies for his clients.



Davin B. Guinn is an associate in Sterne Kessler’s Trial & Appellate Practice Group. Davin has extensive experience across a broad spectrum of litigation proceedings, including hearings and trials, fact and expert discovery, taking depositions, preparing expert witnesses, performing validity and infringement analyses, assessing claim construction positions, and drafting briefs and motions. A growing part of Davin’s practice includes analyzing various litigation elements unique to Section 337 investigations, including the economic prong of the domestic industry requirement, bond analysis, inventory, and remedial order enforcement.



Brooke N. McLain is an associate in Sterne Kessler’s Trial & Appellate Practice Group. She concentrates her practice in the area of patent litigation, including matters before federal district courts and the U.S. International Trade Commission. Brooke has experience handling matters in areas such as ANDA pharmaceutical litigation and the automotive industry. While attending J. Reuben Clark Law School, Brooke served for two years as an editor for the BYU Law Review.



Cristen Corry is an associate in Sterne Kessler’s Trial & Appellate Practice Group. Her practice focuses on patent litigation matters in the federal district courts and the U.S. International Trade Commission. She has experience in legal research, motion practice, and written discovery. Cristen graduated from George Mason University – Antonin Scalia Law School with a concentration in Patent Law. While in law school, Cristen was a member of the Scalia Law Moot Court Board and the Intellectual Property Law Society.



Jamie Dohopolski is an associate in the Trial & Appellate Practice Group and focuses her practice on patent litigation. Jamie graduated from Stanford Law School, where she was an editor of Stanford Law Review and a member of Women of Stanford Law. She clerked for the Hon. Sharon Prost of the U.S. Court of Appeals for the Federal Circuit.

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

BY DAVIN B. GUINN AND PAUL A. AINSWORTH

The year 2023 was marked by two landmark Commission determinations resulting in exclusion orders and cease and desist orders against a popular consumer wearable—the Apple Watch. Both investigations focused on health monitoring technologies offered by the device, and, as a consequence, public interest considerations pulsed through the parties’ briefing and the Commission’s decisions.

The main takeaway from these recent decisions is that the Commission continues to apply a high standard for the public interest inquiry and remains reluctant to withhold remedial orders on the basis of public interest, even if it means excluding highly popular consumer devices. Of particular note is the Commission’s broad view of what qualifies as a reasonable substitute, as it found that reasonable substitutes existed even if it required a consumer to purchase multiple devices to achieve the same functionality and even if the substitute devices lacked the same regulatory approval as the Apple Watch for the asserted health-monitoring features.

I. AliveCor v. Apple¹

On April 20, 2021, AliveCor, Inc. filed a complaint against Apple accusing the Apple Watches with electrocardiogram (ECG) functionality of infringing three U.S. patents pertaining to methods for arrhythmia tracking and discordance monitoring. The principal technology at issue involved the ability to take an ECG reading on a wearable device and perform a heartrate analysis to detect heart conditions such as episodes of atrial fibrillation (AFib). The ALJ ultimately issued a Corrected Initial Determination finding a violation of Section 337 and recommended issuance of a limited exclusion order and cease and desist order. The parties petitioned for review, and the Commission issued a standard notice requesting submissions on the public interest.

A. Public Interest Arguments

The parties and numerous non-parties submitted public interest comments in response to the Commission’s notice. Thereafter, the Commission issued a notice of determination to review in part the ALJ’s determination and expressed particular interest in (1) arguments responsive to already submitted public interest statements and (2) receiving more information regarding the availability and capacity of alternatives to replace the infringing products.

1. AliveCor’s Public Interest Position

AliveCor argued the remedies would promote innovation, competition, and intellectual property rights. They would not adversely affect the public health or economic competition because other suppliers offered substitute wearable heart monitoring devices (*e.g.*, Samsung and Fitbit’s FDA-cleared smartwatches). AliveCor noted that Apple could still sell its non-infringing Apple Watches, which could be combined with AliveCor’s KardiaBand System. It further suggested that Apple could seek a license from AliveCor or design around the infringing feature. According to AliveCor, Apple’s arguments pertaining to the lifesaving nature of the Apple Watches were overstated. AliveCor reiterated that not all health monitoring features of the Apple Watch were found to infringe—only those with both (1) PPG-based arrhythmia detection features (*i.e.*, the Irregular Rhythm Notification (IRN) feature and the High Heart Rate Notification (HHRN) feature) *and* (2) the ECG App, would be subject to the remedial orders. Apple Watch products with IRN and HHRN but no ECG functionality would not be excluded. Relatedly, it opposed Apple’s definition of suitable alternatives as consisting of solely wearable devices with FDA-cleared IRN *and* ECG functionalities, arguing Apple divorced the scope of suitable substitutes from the full scope of available consumer products and pushing back on the notion that all functionalities had to be included within a single device. AliveCor further

¹ *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*, Inv. No. 337-TA-1266.

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

argued that an exclusion order would not impact existing users or interrupt any ongoing medical research involving existing Apple Watch users. Finally, it argued against delayed imposition of a remedy as well as any carve-outs or exemptions.

2. Apple's Public Interest Position

Apple argued the remedies would restrict the availability of FDA-authorized, lifesaving technology. It referenced testimonials of such incidents and cited data on the number of Apple Watch users activating the ECG application and who receive daily AFib warnings. It argued that limiting the availability of these features could increase healthcare costs. Moreover, exclusion would disrupt research efforts and ongoing clinical studies. It argued that reduced competition could lead to higher-priced wearables. Apple focused on the multi-faceted nature of its Apple Watches and its ability to allow millions of wearers to do many things unrelated to *AliveCor*'s patented technology. For example, Apple noted that its Apple Watches have other health features that benefit the

public, which could become unavailable. The remedial orders could also lead to increased unemployment in Apple Watch-reliant industries. And exclusion would result in a supply shock, particularly in view of potential manufacturing constraints. Apple further noted the FDA approval process could take years for new devices, and suggested a delayed remedy would allow for replacements to become more readily available. It defined suitable alternatives as devices that had a specific combination of health features and FDA approval, including the ECG technology at issue. Specifically, Apple argued that the only suitable alternatives would comprise wearable devices with both FDA-cleared ECG and IRN functions. According to Apple, only the Fitbit Charge 5 and Sense fell into that category as having HHRN and both FDA-cleared ECG and IRN features, which products Apple argued were markedly inferior, even assuming Fitbit could ramp up their production. Finally, Apple also sought an exemption for warranty, service, replacements, and repairs.



**View The Recent Five-Part Webinar Series
"Navigating the Intricacies of 337 Litigation
at the International Trade Commission"**

Scan the QR code on page 2 to access this and other on-demand webinars.

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

continued

B. The Commission's Determination on the Public Interest

On December 22, 2022, the Commission issued its notice of Final Determination finding a violation of Section 337, a limited exclusion order, and a cease and desist order. However, the Commission suspended enforcement of these orders pending final resolution of the PTAB's Final Written Decisions, which found the asserted claims unpatentable.

The Commission determined current users of the infringing Apple Watches would be unaffected by the remedial orders and would further maintain access to the non-accused features of those devices. By extension, ongoing research based on these existing devices would be unaffected. It noted that new research could utilize any of the numerous available alternatives. The Commission evaluated Apple's contention that suitable alternatives must (1) have ECG, IRN, and HHRN features; (2) be wearable; and (3) have FDA clearance. But it determined that wearable devices with IRN and HHRN functionalities in conjunction with portable ECG devices also constituted a reasonable alternative. The Commission did not credit Apple's argument that FDA-clearance was mandatory for alternatives to constitute suitable substitutes. Even still, the Commission noted that substitutes with FDA clearance existed. The Commission observed that its PTAB-related suspension would allow time for alternatives to become readily available. It expressed its opinion that competitive conditions would not be harmed, especially in view of the number of alternative products. Lastly, it included an exemption for Apple's service, repair, and replacement obligations.²

² **PTAB Appeals:** As previously noted, enforcement of the Commission's remedial orders is currently suspended until final resolution of the PTAB's Final Written Decisions, which found the asserted claims to be unpatentable. See *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00971, U.S. Patent No. 10,595,731, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022); *Apple, Inc. v. AliveCor, Inc.*, IPR2021-00972, U.S. Patent No. 10,638,941, Final Written Decision Determining All Challenged Claims Unpatentable (Dec. 6, 2022). *AliveCor* appealed both Final Written Decisions on February 7, 2023. Appeals from the PTAB decisions are pending before the Federal Circuit.

II. *Masimo v. Apple*³

On June 29, 2021, the Masimo Corporation filed a complaint against Apple, accusing the Apple Watch Series 6 (and later models) with light-based pulse oximetry functionality of infringing five U.S. patents. The technology at issue involved physiological measurement devices that rely on the transmission of light through body tissue to monitor and report physiological signals. Masimo's asserted patents were directed to devices used for non-invasive measurement of physiological parameters such as blood oxygen saturation (or pulse oximetry) and thermal mass technology. The ALJ ultimately issued a Final Initial Determination finding a violation of Section 337, upon which both parties petitioned for review. The ALJ further recommended the issuance of a limited exclusion order and cease and desist order. The Commission issued a standard notice requesting submissions on the public interest.

A. Public Interest Arguments

The Commission's request resulted in 31 non-party public interest comments, as well as Masimo and Apple's public interest statements. Seven (7) additional non-party submissions came after the Commission issued its notice of determination to review in part the ALJ's Final Initial Determination, wherein it requested written submissions, at least from the parties, regarding the public interest factors. In particular, the Commission set forth a list of public-interest-related questions on a variety of issues, including the effects of any remedial order on medical research, how the Commission should define a reasonable substitute, and the ease of design-around options.

ITC Appeals: In addition, both *AliveCor* and *Apple* appealed the Commission's Final Determination to the Federal Circuit. See *AliveCor, Inc. v. ITC*, Appeal No. 23-1509 (Fed. Cir.); *Apple Inc. v. ITC*, Appeal No. 23-1553 (Fed. Cir.). Those appeals are currently pending.

³ *In the Matter of Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276.

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

1. *Masimo's* Public Interest Position

Masimo argued the remedies would promote investment in life-saving technologies and discourage “efficient infringement.” It argued Apple should be estopped from arguing public interest concerns because of the Commission’s rejection of similar public interest arguments in *AliveCor*. It observed that the infringing Apple Watches did not contain FDA-cleared pulse oximetry, and the non-accused Apple Watch SE with its various features would remain on the market. Masimo identified a variety of companies that offered smartwatches with pulse oximetry, including the Masimo W1, as well as smartwatches capable of pairing with pulse oximetry sensors. In this regard, it referenced the Commission’s determination in *AliveCor* in arguing that reasonable substitutes should be defined as watches with a range of health, safety, and wellness features. It also argued that reasonable substitutes should be defined by the protected interest in the features benefitting the public health and welfare, further arguing that consumers’ health and welfare did not depend on watch capabilities such as making phone calls, sending emails and text messages, showing news and weather updates, and other such features. And it argued there was no evidence that other manufacturers lacked the capacity to meet increased demand. Masimo suggested that Apple could remove the infringing feature, and argued that U.S. consumers would benefit from the remedial orders because of the feature’s poor performance. Masimo argued against any service, repair, or replacement exemption, indicating a refund as set forth in Apple’s warranty terms would be sufficient. It also opposed Apple’s request for a 12-month delay in implementation of the recommended remedial orders.

2. *Apple's* Public Interest Position

Apple countered that it was not collaterally estopped because different public interest concerns were at issue. It argued that Masimo was attempting to narrow the set of features relevant to the public interest inquiry solely to health, safety, and wellness features. It referenced numerous features it argued were pertinent to the reasonable substitute inquiry, including general smartwatch capabilities, fitness tracking features, as well as health and wellness features. It posited that customers buy Apple Watches to obtain combinations of desired features, which would affect a consumer’s consideration of alternative products. Hence, there could be a broad range of reasonable substitutes, but the consumer would not be able to purchase alternatives with the same set of features and quality as the excluded Apple Watches. Relatedly, it argued the Masimo W1 was not a reasonable substitute because of (1) its overall unavailability to U.S. consumers in terms of material quantity, (2) it was not a smartwatch in the sense that it lacked the communications and numerous other features provided by the Apple Watches accused of infringement, (3) it had not been shown to take reliable measurements of physiological parameters, and (4) it was not sufficiently manufactured to meet the increased demand caused by an exclusion order. Apple also argued the remedial orders would not only limit future access to its blood oxygen feature, but would also limit future access to other health features and other more general functionalities. Apple argued again that the remedial orders would interfere with medical research. It emphasized that a multi-year shortage would occur without delayed implementation, and there was no evidence that other manufacturers could meet increased demand. It asked for a 12-month delay to allow others to scale up production. Exclusion would also reduce the number of choices available and lessen competition for new purchasers. Finally, Apple requested a warranty exemption for service, repair, and replacement.

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

continued

B. The Commission's Determination on the Public Interest

On October 26, 2023, the Commission issued a notice of its Final Determination finding a violation of Section 337, a limited exclusion order, and a cease and desist order. The Commission included a warranty exemption for service, repair, and replacement, but ultimately determined the public interest factors did not preclude issuance of these remedial orders. In its Opinion, the Commission concluded that Apple was not collaterally estopped. It further determined that any adverse effect on the public health could be mitigated by its service, repair, and replacement exemption. The Commission further determined there were numerous available substitutes, including the Masimo W1 and Masimo Freedom watches, and Apple failed to show that manufacturers could not ramp up their production.

With respect to the scope of reasonable alternatives, the Commission observed that such scope is assessed "from the perspective of public interest concerns raised in an investigation." It acknowledged Apple's argument that consideration of the public health and welfare should take into account the exclusion of the infringing Apple Watches' ECG feature because it too was present in all of the infringing products.

The Commission defined "reasonable substitutes" to include those offering a range of health, safety, and wellness features (e.g., measuring blood oxygen levels or recording ECGs), but noted a single device did not need to be able to measure oxygen levels and record ECGs. The inconvenience of having to wear two wearable devices did not amount to a public interest concern. The Commission indicated that Apple had stretched the public health and welfare factor too far by including features with connections too far removed from the public health and welfare (e.g., telecommunications features) as part of the requirements for a reasonable substitute. The Commission referenced prior precedent in noting that the correct analysis for reasonable substitutes is not whether the exact device can be obtained by every consumer. In listing products within the scope of reasonable substitutes, the Commission noted that its list of products "alone or combined with each" included either "one or both of the blood oxygen features and the ECG features (as well as the IRN, HHRN, or other features), and thus are reasonable substitutes." Regarding medical research at various stages, the Commission found there would be no meaningful effect. For example, the remedial orders would not prevent current study

Sterne Kessler recognized for its national ITC litigation practice, and "Highly Recommended" for Patent Disputes in the District of Columbia. *Managing IP* has recognized the firm for achievements in intellectual property law in its "IP Stars" guide every year since 2014.

- Managing IP "IP Stars 2023"

The Public Interest Impact - Considerations from *AliveCor* and *Masimo*

participants from continued participation. They could fix or replace their watches if necessary because of the service, repair, and replacement exemption. In terms of competitive conditions and U.S. consumers, the Commission found there would be no adverse impact because of the numerous suitable alternatives. Moreover, there would be no public interest concern with respect to U.S. consumers in view of the service, repair, and replacement exemption. The Commission did not impose a 12-month delay.⁴

III. Considerations from *AliveCor* and *Masimo*

The Commission's determinations in *AliveCor* and *Masimo* maintain the high public interest threshold that is rarely overcome when seeking to avoid implementation of exclusionary relief at the ITC. The health-related features of the accused products in each of these investigations present one of the most compelling public interest cases since the Obama Administration's 2013 disapproval of the Commission's remedial orders in the *Samsung v. Apple* dispute

involving the iPhone and iPad.⁵ However, in the *AliveCor* and *Masimo* investigations, the U.S. Trade Representative, as delegated by the President, took no action with respect to the Commission's Final Determinations. Given the popularity of the Apple Watch, it is no surprise that the Commission appeared to give greater scrutiny to the public interest considerations raised by the parties and the public. Nevertheless, the Commission's reasoning in both investigations suggests that public interest concerns remain a difficult path for preventing the issuance of exclusion orders once a Section 337 violation has been established.

4 On October 30, 2023, Apple filed a motion to stay the limited exclusion order and cease and desist order pending appeal and/or in light of the potential government shutdown. In this motion, Apple made various public interest arguments. Masimo opposed Apple's motion on November 9, 2023, arguing in large measure that the Commission already considered and rejected Apple's public interest arguments. On November 20, 2023, Masimo also submitted a request for judicial notice of the FDA's regulatory determination on November 17, 2023, which made the Masimo W1 Watch the only FDA-cleared over-the-counter pulse oximeter. But on December 20, 2023, the Commission denied Apple's motion to stay (without reliance on the materials that Masimo submitted as part of its request for judicial notice). In its January 3, 2024 supporting opinion, the Commission found that the public interest counseled against a stay, noting (1) that it already considered and rejected Apple's public interest arguments in its final determination and (2) the exclusion of infringing products to protect intellectual property rights is favored by the public interest.

Apple's appeal to the Federal Circuit was docketed on December 26, 2023—the day after the Presidential Review Period expired on December 25, 2023—and on that same day, Apple filed (1) a non-confidential emergency motion for an immediate interim stay pending disposition of motion for stay pending appeal, and (2) a non-confidential emergency motion to stay enforcement of the ITC's orders pending review. In the former motion, Apple sought an interim stay for the time required to resolve the second, concurrently filed stay motion, or at least until the Exclusion Order Enforcement Branch could issue a decision regarding Apple's redesign for the excluded products. Apple noted that the Exclusion Order Enforcement Branch was set to determine whether a redesigned version of the excluded Apple Watch products is within the scope of the remedial orders on January 12, 2024. Apple also incorporated its reasoning from the second stay motion, which raised various arguments, including an assertion that the public interest supported a stay. The Commission and Masimo submitted letters on December 26, 2023, opposing both stay motions. But on December 27, 2023, the Federal Circuit granted Apple's motion for an interim stay, temporarily staying the remedial orders and directing the government not to enforce them "until further notice while the court considers the motion for a stay pending appeal." See *Apple Inc. v. ITC*, Appeal No. 2024-1285, ECF No. 19, Order at 2 (Fed. Cir. Dec. 27, 2023).

5 *In the Matter of Certain Electronic Wireless Devices, including Wireless Communication Devices, Portable Music and Data Processing Devices, and Tablet Computers*, Inv. No. 337-TA-794, Letter from USTR (Aug. 3, 2013).

Looking Beyond Inventory Numbers to Secure a Cease and Desist Order

BY JOSEPHINE KIM AND CRISTEN A. CORRY

The Commission may grant a cease and desist order (“CDO”) when it finds a violation of Section 337. See 19 U.S.C. 1337(f)(1). Historically the Commission would grant a CDO upon a showing that a respondent had a “commercially significant inventory” in the United States of infringing products that could undercut the remedy provided by an exclusion order. However, in recent years the Commissioners have debated the legal requirement for a CDO, especially because the language of section 337(f)(1) leaves the issuance of a CDO to the Commission’s discretion and does not require that a certain test or standard be met, as long as there are no public interest concerns.¹

In view of the increase in e-commerce and the rising challenges of keeping infringing products out of the United States marketplace, the Commission is increasingly considering evidence beyond inventory numbers when issuing CDOs. For example, the Commission will consider the unique factual context to issue a CDO even when there is only one unit in inventory.² The Commission may also consider “significant domestic operations” as a stand-in to show that inventory in the United States is quickly replenished even if absolute inventory numbers are low or unavailable.³ Therefore, it is important for complainants to gather pertinent facts during pre-complaint investigation (for defaulting respondents) or during the investigation’s discovery period (for contesting respondents) to support a CDO case.

For Complainants Seeking a CDO Against Defaulting Respondents

The Commission has articulated a more lenient standard with regards to CDO when it comes to defaulting respondents because it is difficult, if not impossible, for complainants to obtain inventory information when the respondent refuses to participate in the investigation. The Commission will examine the record, including the facts alleged in the complaint that are deemed to be true, in addition to any other facts the complainant is able to obtain, and will draw inferences in favor of complainant to provide the necessary relief as to defaulting respondents.⁴

In the case of domestic defaulting respondents, the Commission has consistently inferred the presence of commercially significant domestic inventories.⁵ For example in *Mobile Device*, the Commission determined that because three domestic defaulting Respondents maintained addresses in the United States, it was proper for the Commission to infer that the domestic Respondents had commercially significant inventory and significant domestic operations.⁶ Similarly in *Earpiece Devices*, the Commission articulated that it is “the Commission’s practice of inferring significant inventories or domestic operations as to named respondents in the United States who fail to participate in an investigation,” and because of this practice, the Commission issued CDOs against the domestic defaulting respondents.⁷

1 See *Certain Dental Implants*, Inv. No. 337-TA-934, Comm’n Op. at 49-51 (May 11, 2016) (Commission not issuing a CDO because the Commissioners were divided 3-3 on whether a CDO was appropriate).

2 See *Certain Automated Put Walls and Automated Storage and Retrieval Systems, Associated Vehicles, Associated Control Software, and Component Parts Thereof*, Inv. No. 337-TA-1293, Comm’n Op. at 33-34 (August 17, 2023) (finding the domestic inventory of one system is significant where the area of technology deals with specifically expensive, customized sorting systems for which prebuilt inventory is uncommon, such as in the field of automated material-handling systems). In this instance, the Commission also noted that one infringing unit in inventory represented 33% of the total imported units, and 50% of all units sold to date. *Id.*

3 See *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Thereof*, Inv. No. 337-TA-977, Comm’n Op. at 16-17 (April 28, 2017) (stating that a CDO would be a proper remedy if Complainant could show Respondent had “significant domestic operations” within the United States).

4 See *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Thereof*, Inv. No. 337-TA-977, Comm’n Op. at 17-18 (Apr. 28, 2017).

5 See, e.g., *Certain Toner Supply Containers and Components Thereof (I) (“Toner Supply”)*, Inv. No. 337-TA-1259 Comm’n Op. at 20-21 (Aug. 19, 2022); *Certain Earpiece Devices and Components Thereof (“Earpiece Devices”)*, Inv. No. 337-TA-1121, Comm’n Op. at 41-42 (Nov. 8, 2019); *Certain Hand Dryers and Housing for Hand Dryers*, Inv. No. 337-TA-1015, Comm’n Op. at 24 (Oct. 30, 2017); *Certain Mobile Device Holders and Components Thereof (“Mobile Device Holders”)*, Inv. No. 337-TA-1028, Comm’n Op. at 27 (Mar. 22, 2018); *Certain Agricultural Tractors, Lawn Tractors, Riding Lawnmowers, and Components Thereof*, Inv. No. 337-TA-486, Comm’n Op. at 18 (Aug. 14, 2003); *Certain Rare-Earth Magnets and Magnetic Materials and Articles Containing Same*, Inv. No. 337-TA-413, USITC Pub. No. 3307, Comm’n Op. at 17-18 (May 2000).

6 See *Certain Mobile Device Holders and Components Thereof (“Mobile Device”)*, Inv. No. 337-TA-1028, Comm’n Op. at 27 (Mar. 22, 2018).

7 *Earpiece Devices*, Comm’n Op. at 41.

Looking Beyond Inventory Numbers to Secure a Cease and Desist Order

In contrast, the Commission will not automatically presume the presence of domestic inventories for foreign defaulting respondents. Instead, the Commission will assess whether the complaint alleges facts that support the inference that the defaulting foreign respondent maintains significant inventories in the U.S. For example, in *Liquid Crystal eWriters*, the Commission issued CDOs based on “allegations in the complaint that foreign defaulting respondents maintain commercially significant U.S. inventories and/or are engaging in significant commercial business operations in the United States.”⁸

The Commission has recognized that “because the foreign respondents have defaulted, it is difficult for complainants to obtain detailed discovery to establish record evidence regarding the foreign respondents’ U.S. business operations and agents, including the magnitude, ownership, and distribution channels for U.S. inventories of infringing products, and all reasonable inferences should be granted in favor of the complainant.”⁹ Because of this recognized difficulty, the Commission has been willing to infer significant domestic operations when complainant has shown that a foreign defaulting respondent conducted domestic distribution operations. In *Arrowheads*, the record showed that one shipment of infringing imported articles was shipped domestically from Las Vegas, Nevada and bore a U.S. business address of the foreign defaulting Respondent.¹⁰ From this information about a domestic distribution address, the Commission inferred that the foreign defaulting Respondent conducted significant domestic operations. *See id.*

Similarly, in *Pillows and Seat Cushions*, evidence showing infringing products were likely shipped from China to distribution centers in California allowed the Commission to infer that Respondent had significant domestic operations and significant domestic inventory.¹¹ Here, the record consisted of orders and deliveries of an infringing product from the website Alibaba and UPS shipping labels from the package containing the infringing product with a return address in California.¹² Chairman Johanson and Commissioner Kearns found that “this evidence, particularly the U.S. return address, demonstrates sufficient domestic commercial activity to warrant the imposition of a cease and desist order.”¹³

But, the Commission is unwilling to go as far as to “presume the presence of domestic inventories or other business operations in the United States” that would warrant a CDO.¹⁴ The record must show more than foreign defaulting respondents simply having some contacts within the United States. *See, e.g., Arrowheads*, Comm’n Op. at 21-22. For example in *Arrowheads*, the record showed certain foreign defaulting respondents had English language websites and those respondents conducted communications via email with a purchaser in the United States.

⁸ *Certain Liquid Crystal eWriters and Components Thereof (“Liquid eCrystal Writers”)*, Inv. No. 337-TA-1035, Comm’n Op. at 6 (Sept. 26, 2017). *See also Certain Pillows and Seat Cushions (“Pillows and Seat Cushions”)*, Inv. No. 337-TA-1328, Comm’n Op. at 9-10 (Nov. 13, 2023).

⁹ *Electric Skin Care Devices*, Inv. No. 337-TA-959, Comm’n Op. at 30 (Feb. 13, 2017); *see Pillows and Seat Cushions*, Comm’n Op. at 9-10.

¹⁰ *See Certain Arrowheads with Deploying Blades and Components Thereof (“Arrowheads”)*, Inv. No. 337-TA-977, Comm’n Op. at 21 (Apr. 28, 2017).

¹¹ *See Pillows and Seat Cushions*, Comm’n Op. at 12.

¹² *Id.*

¹³ *Id.* Of note, Commissioners Schmidlein and Karpel consider Section 337(g)(1) to be the appropriate authority regarding the issuance of CDOs as to both domestic and foreign defaulting Respondents. *See, e.g., Toner Supply Containers*, Inv. No. 337-TA-1259, Comm’n Op. at 22 (Aug. 18, 2022). In other words, they support the issuance of CDOs as long as the criteria under subsection 337(g)(1)(A)-(E) are met (i.e., (1) a respondent must be named in the complaint and the respondent is either served or refused service of the complaint and notice of investigation; (2) the respondent fails to show good cause why it should not be held in default for failing to respond to the complaint and notice of investigation, and (3) complainant must request that the CDO be limited to the defaulting respondent in its initial submission on remedy, bonding, and the public interest). *Id.*

¹⁴ *Earpiece Devices*, Comm’n Op. at 42 (*citing Mobile Device*, Comm’n Op. at 24).

Looking Beyond Inventory Numbers to Secure a Cease and Desist Order

continued

See *id.* at 21. The record was supplemented with shipping labels that indicated these specific foreign defaulting respondents directly shipped infringing products to U.S. customers of infringing products from China. See *id.* The Commission found this evidence insufficient by itself to establish either significant domestic activities or operations in the United States to warrant a cease and desist order. See *id.* at 22. Rather, the Commission determined that this evidence only indicated that the foreign defaulting respondents had contacts within the United States. See *id.*

Therefore, while the Commission will presume that domestic defaulting respondents maintain commercially significant inventories in the United States, the complainant must provide some more information if it hopes to secure a CDO as to a foreign defaulting respondent. Evidence of U.S. distribution centers or even shipping labels evidencing a U.S. distribution site are helpful to establish significant domestic operations, but having mere contacts (i.e. customers) within the United States will not suffice to obtain a CDO as to a foreign defaulting respondent.

For Complainants Seeking a CDO Against Contesting Respondents

In contrast, the Commission imposes a more rigorous standard on complainants seeking a CDO against a contesting respondent. A complainant must show that the CDO “is necessary to address the violation found in the investigation so as to not undercut the relief provided by the exclusion order.”¹⁵ In order to satisfy this burden, the complainant may prove the existence of “significant domestic operations” by showing that the respondent “plays a role in the United States in the sale or distribution of the Accused Products.”¹⁶

¹⁵ *Certain Tobacco Heating Articles and Components Thereof (“Tobacco Heating”),* Inv. No. 337-TA-1199, Comm’n Op. at 49-50 (Oct. 19, 2021) (citing *Certain Integrated Repeaters, Switches, Transceivers, & Prods. Containing Same*, Inv. No. 337-TA-435, USITC Pub. No. 3547 (Oct. 2002), Comm’n Op. at 27 (Aug. 16, 2002); see also H.R. REP. No. 100-40, at 160 (1987)).

¹⁶ *Tobacco Heating*, Comm’n Op. at 54 (Oct. 19, 2021). Of note, Commissioner Schmidlein does not believe that inventory or domestic operations needs to

In *Tobacco Heating*, the Commission issued a CDO against an active respondent based on the record showing that respondent had significant domestic operations that could undercut the remedy provided by an exclusion order alone.¹⁷ Specifically, the respondent was found to have significant domestic operations because: (1) it was the exclusive licensee for the importation, distribution, and sale of infringing product in the United States; (2) it was involved in preparing and submitting regulatory paperwork to FDA; and (3) it was a Virginia-based company that is an affiliate of a larger USA-based corporation, which had commercially significant inventory of the infringing product.¹⁸ Further, the Commission determined that respondent, as a domestic corporation and exclusive licensee for distribution and sale of the accused products, “would have an opportunity to undercut an exclusion order, especially in light of the commercially significant inventory already in the United States and . . . [the parent company’s] expansion of infringing product sales . . . during the investigation.”¹⁹ Note, however, that in the same investigation, the Commission declined to issue a CDO against another active Swiss respondent because complainant failed to show that respondent had either a significant domestic inventory or significant domestic operations.²⁰ Although the Swiss respondent had corporate connections to the other domestic respondents, admitted importation, had involvement in the design and manufacture of the accused products, and had consulted on FDA submissions, the Commission found “no evidence as to whether [it] plays a role in the United States in the

be “commercially significant” in order to issue the CDO; rather, she takes the position that the presence of some infringing domestic inventory or domestic operations, regardless of its commercial significance, provides a basis to issue a CDO. *Id.* at 49.

¹⁷ See *Tobacco Heating*, Comm’n Op. at 54 (Oct. 19, 2021).

¹⁸ See *id.* at 52.

¹⁹ *Id.*

²⁰ *Id.*

Looking Beyond Inventory Numbers to Secure a Cease and Desist Order

sale or distribution of the Accused Products.”²¹ This underscores the difficulty of demonstrating significant domestic inventory or operations for foreign contesting respondents without evidence of their sales or distribution work in the U.S.

By contrast, in November of 2023, ALJ Bhattacharyya recommended issuance of a CDO as to a respondent on the basis of significant domestic operations, even though the respondent had no domestic inventory.²² In *Outdoor and Semi-Outdoor*, the ALJ found that respondent, a U.S. company, had domestic operations designing, selling, and delivering the accused products to U.S. customers.

Some takeaways with these investigations are: (i) the importance of building a record of the respondent’s involvement in the sales and distribution of the accused products, even if there is little or no U.S. inventory, (ii) the value of gathering circumstantial evidence of significant domestic operations (e.g., exclusive licensee or an affiliate of other respondents with commercially significant inventory), and (iii) the higher bar for CDOs as to foreign respondents.

Conclusion

Parties should pay attention to the type of evidence detailed above that the Commission finds persuasive when evaluating whether a CDO is warranted. The Commission now considers much more than inventory numbers in its CDO analysis. Moreover, the Commissioners’ debate on the legal requirement for CDOs has been ongoing for several years and would be worth watching for further developments.

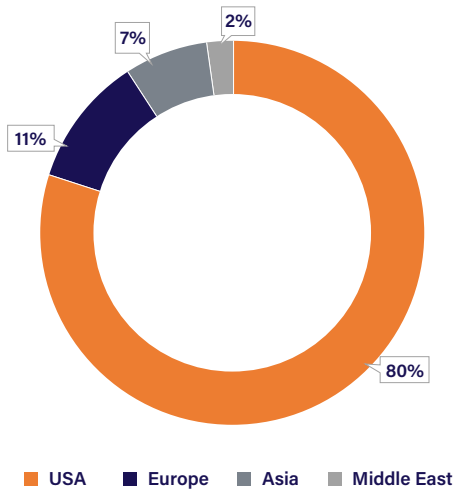
²¹ *Id.*

²² See *Certain Outdoor and Semi-Outdoor Electronic Displays, Products Containing Same and Components Thereof (“Outdoor and Semi-Outdoor”)*, Inv. No. 337-TA-1331, 2023 WL 8664244, Initial Determination (Nov. 27, 2023).

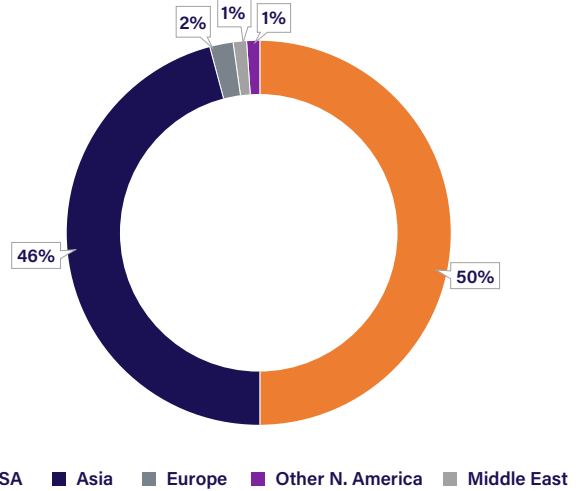
ITC Statistics

Cases Instituted in 2023

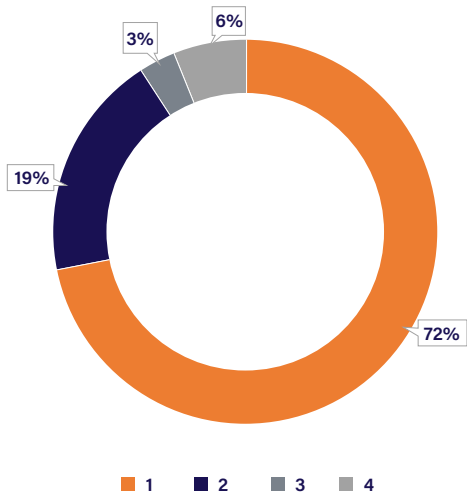
Complainant Region



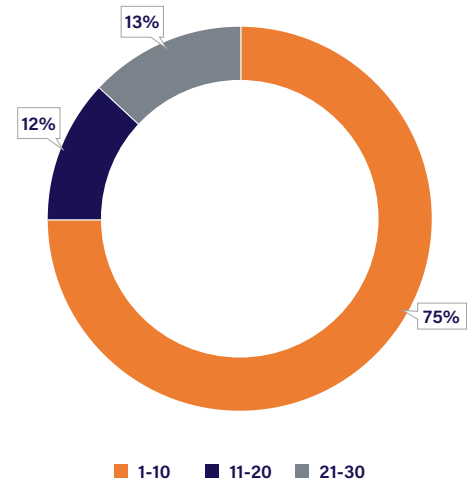
Respondent Region



Complainants per Investigation



Respondents per Investigation



IP Type in Investigations	#	%
Utility Patent	28	88%
Trademark	3	9%
Trade Dress	3	9%
False Advertising	2	6%
Trade Secret	2	6%
False Designation of Origin	2	6%
Design Patent	1	3%
Unfair Competition	1	3%

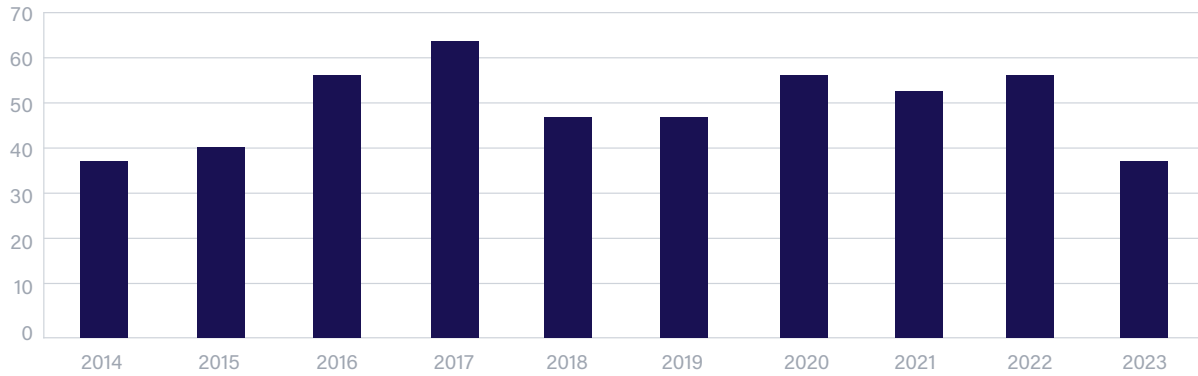
In 2023, on average, from institution...

- 4.6 months to Markman hearing
- 16.6 months to target date
- 17.6 months to Commission opinion

Thank you to Patrick Murray, Josephine Kim, Davin Guinn, Jamie Dohopolski, and Nick Nowak for contributing important data and statistics for this report.

Case Flow and Outcomes

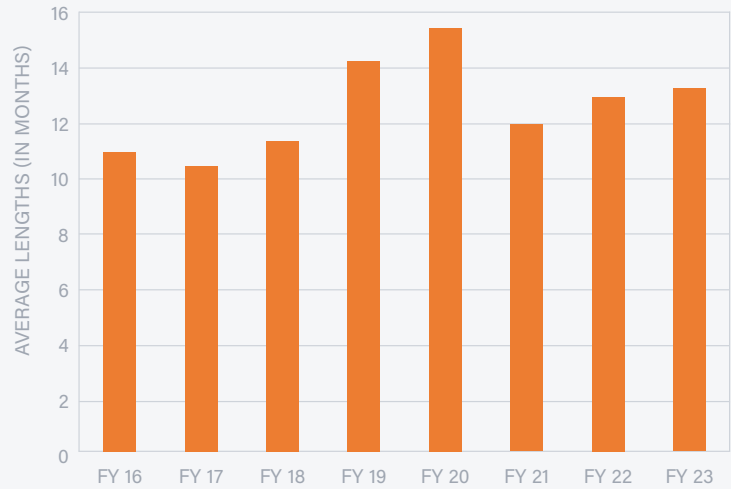
337 Violation Complaints



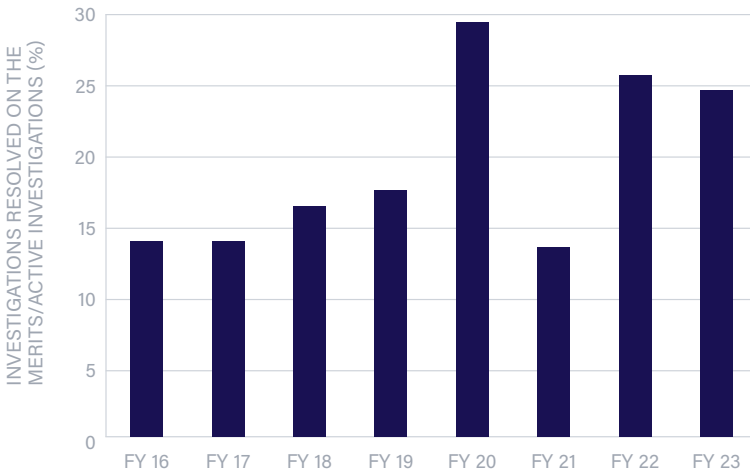
Patents per Investigation In cases with any patents asserted

Comp. Year	Design	Utility
2012	0.1	3.8
2013	0.3	2.8
2014	0.1	3.5
2015	0.3	3.7
2016	0.7	3.1
2017	0.2	3.4
2018	0.1	3.4
2019	0.0	3.4
2020	0.3	3.0
2021	0.8	3.6
2022	0.1	3.1
2023	0.1	3.6
Overall	0.3	3.4

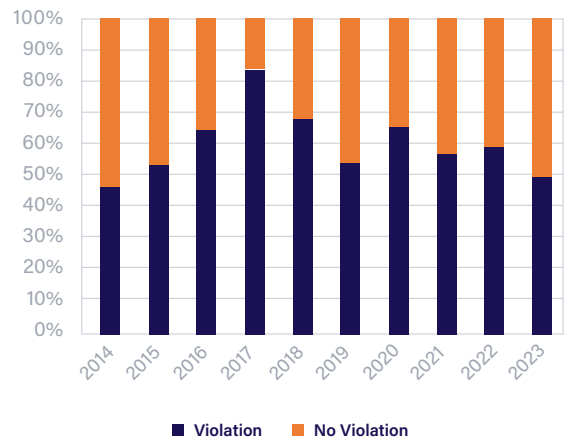
Average Length of Investigation



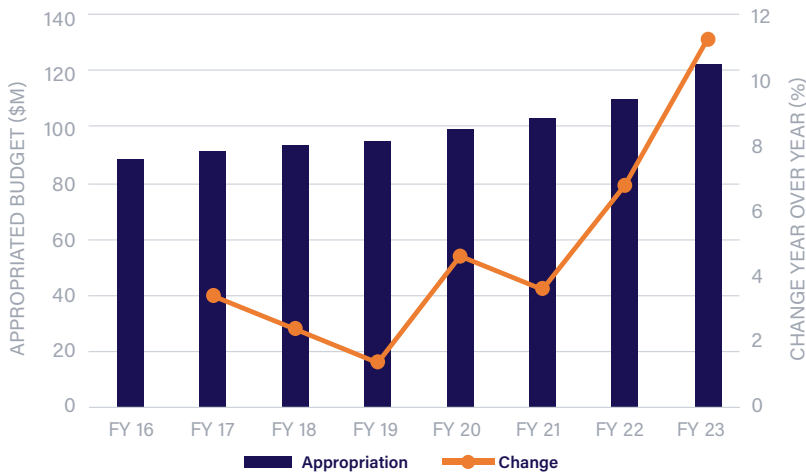
Investigations Resolved on the Merits



Final Determination Outcomes

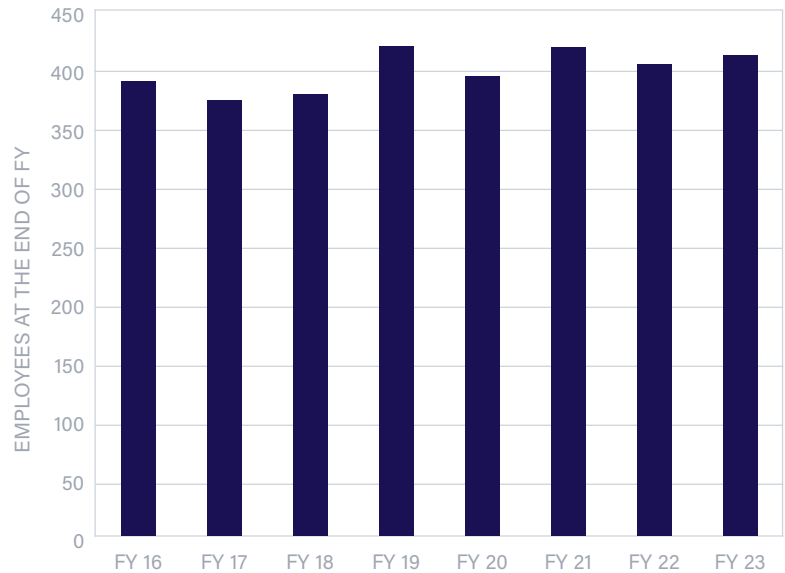


ITC Operations



Congress again increased the ITC's budget for fiscal year 2023. Congress has yet to decrease the ITC's absolute budget, and last year marked the greatest percentage increase in appropriations to the ITC yet.

But the ITC has not used its increased budget to build out its staff. Its staff numbers have remained relatively constant over the last several years. (Note: data for FY 21 is a mid-year figure.)



In comparison to prior years, the ITC had a lower case load in 2023. This does not appear to have any relationship with the average time to resolution, but it could be contributing to the ITC's increased tendency to resolve investigations on the merits. Also notable, the government shutdown in 2019 did not appear to impact the ITC's average length of investigations respective to other years.

Looking forward, however, the ITC may see an increase in its case load should the SECRETS Act gain traction. Introduced in 2021, this bill would expand the ITC's authority beyond patent, copyright, and trademark infringement and enable the ITC to exclude imports that misappropriate trade secrets. But the bill was not reintroduced in the 2022 or 2023, so it appears unlikely that Congress will enact this law in 2024.

Instead, Congress may be inclined to free up more of the ITC's time. Unlike the SECRETS Act, the Advancing America's Interests Act has been reintroduced annually for the last several years, including 2023. But, by making it more difficult to prove domestic industry, this bill would likely allow the ITC to resolve cases more quickly by obviating the need to reach the merits of alleged infringement.

A Pair of Section 337 Investigations Involving Automotive Lamps Illuminated the Potential of Design Patents

BY IVY CLARICE ESTOESTA

Design Patent Trends at the ITC

The trend of the US International Trade Commission issuing remedial orders for design patents at higher percentages than for utility patents continued in 2023.¹ From 2015-2023, 356 such investigations were concluded. And of those 356 investigations, 187 cases proceeded to Final Determination. The Commission found a violation and issued Remedial orders in 112 of the 187 cases. From 2015 through 2023, the Commission issued General Exclusion Orders (GEO) in 65% of the design patent cases that went to Final Determination, compared to 13% for Section 337 investigations asserting utility patents. Additionally, the Commission issued Limited Exclusion Orders (LEO) in 40% of the Final Determinations involving design patents, compared to 44% for Section 337 investigations asserting just utility patents or other unfair acts. Finally, the Commission issued Cease-and-Desist Orders (CDO) in 65% of Section 337 investigations involving design patents, compared to 41% for Section 337 investigations asserting just utility patents or other unfair acts.

GEO in Section 337 investigations, 2015 - 2023

	Did Not Assert Design Patents	Asserted Design Patents	Grand Total
No GEO	145	7	152
Issued GEO	22	13	35
Grand Total	167	20	187

LEO in Section 337 investigations, 2015 - 2023

	Did Not Assert Design Patents	Asserted Design Patents	Grand Total
No LEO	94	12	106
Issued LEO	73	8	81
Grand Total	167	20	187

¹ For more information on past data on Design Patents at the ITC, please review last year's report here: <https://www.sterneckesler.com/news-insights/publications/2022-design-patents-year-review-analysis-and-trends>

Certain Replacement Automotive Lamps I and II

The Commission issued one GEO in a design patent case in 2023. The low number was likely due to the fact that Complainants did not seek a GEO in two major 337 investigations involving design patents that were initially expected to terminate this year: *Certain Replacement Automotive Lamps* (Inv. No. 337-TA-1291) and *Certain Replacement Automotive Lamps II* (Inv. No. 337-TA-1292).² In those investigations, Complainants Kia and Hyundai each sought only a LEO and CDO against the named respondents, TYC Brother Industrial Co., Genera Corporation, LKQ Corporation of Chicago, and Keystone Automotive Industries (collectively, "Respondents"). Though Inv. Nos. 337-TA-1291 and 337-TA-1292 have not yet concluded, the Initial Determinations ("ID") issued in those investigations found none of the asserted patents to be invalid as anticipated or obvious, and found a violation of section 337 by Respondents with respect to 17 of Kia's 20 asserted design patents for various automobile lamps and with respect to all 21 of Hyundai's patents for various automobile lamps. Both IDs recommended issuing a LEO should the ITC find a violation, but not a CDO because the evidentiary record did not demon-

CDO Section 337 investigations, 2015 - 2023

	Did Not Assert Design Patents	Asserted Design Patents	Grand Total
No CDO	99	7	106
Issued CDO	68	13	81
Grand Total	167	20	187

Final Determinations for Section 337 investigations, 2015 - 2023

	Did Not Assert Design Patents	Asserted Design Patents	Grand Total
No Violation	73	2	75
Violation	94	18	112
Grand Total	167	20	187

² In December 2023, the Commission extended the target date for these investigations to February 2024.

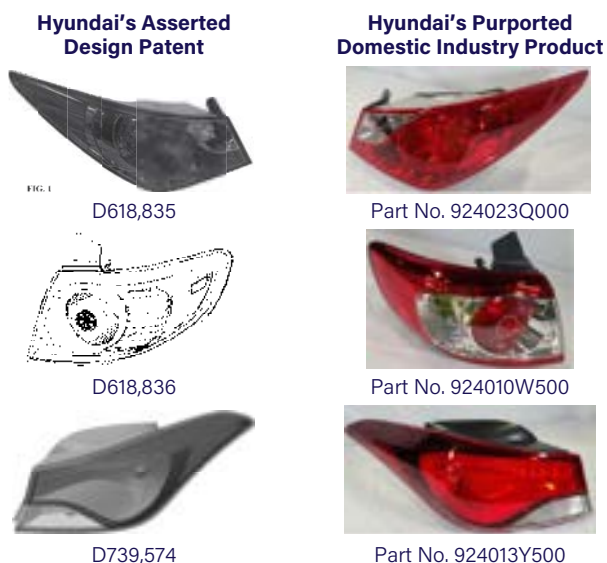
A Pair of Section 337 Investigations Involving Automotive Lamps Illuminated the Potential of Design Patents

continued

strate that Respondents maintain a commercially significant inventory of infringing products in the United States.

Respondents challenged Complainants Hyundai's and Kia's contentions that they satisfy the technical prong of the domestic industry requirement. The technical prong requires that the complainant "show that there is a domestic industry product that actually practices at least one claim of the asserted patent." *Broadcom Corp. v. ITC*, 28 F.4th 240, 250 (Fed. Cir. 2022). Respondents argued that the asserted patents at issue depict—and therefore claim—either a passenger- or a driver-side lamp, and thus, Complainants' purported representative domestic industry products depicting the mirror image of the patented designs do not practice the designs claimed in the asserted patents.

The administrative law judge (ALJ) presiding over Inv. No. 337-TA-1292 determined that under the proper inquiry—whether an ordinary observer would find the overall visual impression of the patented design and the mirror image domestic industry product design to be substantially similar—the overall visual impressions of the claimed designs of the asserted patents and the corresponding mirror image domestic industry products at issue are substantially the same, and therefore, Hyundai satisfies the technical prong of the domestic industry requirement. Compare representative images of some of Hyundai's patented designs and their purported domestic industry products, below.



The ALJ presiding over Inv. No. 337-TA-1291 reached the same conclusion. Declining to limit scope of the Asserted Kia patents to the specific passenger-/driver-side of the lamp shown and relying on expert testimony that an ordinary observer would find the overall visual impression of patented design and the corresponding mirror image domestic industry product design to be substantially similar, the ALJ found that Kia satisfied the technical prong of the domestic industry requirement. Compare representative images of some of Kia's patented designs and their purported domestic industry products, below.



However, the ALJ found that Kia failed to satisfy the technical prong of the domestic industry requirement for three of its asserted patents: D781,471; D749,757; and D705,963. According to the ALJ, D'471 and D'757 include a prominent flange that is not practiced by their corresponding purported domestic industry products, and D'963 lacks surface patterns that are present in the purported domestic industry product. Compare representative images of the D'471, D'757, and D'963 Patents and their purported domestic industry products, below. The images of the D'471, D'757, and D'963 Patents are marked up to indicate their substantial visual differences with their purported domestic industry products.

Kia might have improved its ability to satisfy the technical prong for these three patents had the prominent flange (in the D'757 and D'963 Patents) and the lower area (in the D'963 Patent) been drawn in broken lines to

A Pair of Section 337 Investigations Involving Automotive Lamps Illuminated the Potential of Design Patents

Kia's Asserted Design Patent



D781,471



D749,757



D705,963

Kia's Purported Domestic Industry Product



Part No. 92402A9020



Part No. 92402D9020



Part No. 924011U500

indicate that they are disclaimed subject matter. Armed with the knowledge that succeeding in a Section 337 investigation requires satisfying the technical prong of the domestic industry, a design patent applicant should consider prospectively drafting its design patent applications to satisfy the technical prong. This includes ensuring that the design application drawings depict the to-be commercialized embodiment before filing, or using broken lines (or other drawing conventions) in the design patent application drawings to disclaim elements that might not yet be finalized in the to-be commercialized design when filing the design application drawings.

Applicability of ITC Severance Rules

The significant number of design patents at issue in

each Inv. Nos. 337-TA-1291 and 337-TA-1292 (at least 20 in each investigation) is remarkable in that it did not trigger subjecting either investigation to the ITC's severance rules. Those severance rules permit the Commission or an ALJ to sever an investigation into multiple investigations voluntarily, or upon a motion from any party in the investigation, when a "complaint alleges a significant number of unrelated technologies, diverse products, unrelated patents, and/or unfair methods of competition or unfair acts such that the resulting investigation, if implemented as one case, may be unduly unwieldy or lengthy." Rules of General Application, Adjudication and Enforcement (issued April 26, 2018) at 11. See also 9 C.F.R. §210.10(a)(6), §210.14(h). Although there are no pre-set cut-offs to sever an investigation, for Complainants considering filing an investigation, asserting no more than five patents per investigation serves as a useful rule-of-thumb.

Since being adopted in 2018, the rules of severance have been raised in three investigations³, though only one investigation appears to have been severed. *Light-Emitting Diode Products, Systems, and Components Thereof (I)*, Inv. No. 337-TA-1163, which involved seven patents and one false advertising claim, was severed into three co-pending ITC investigations. Though the ITC's severance rules did not come into play in Kia's and Hyundai's Inv. Nos. 337-TA-1291 and 337-TA-1292, a design patent holder should be mindful that investigations involving solely design patents are not exempt from the severance rules and weigh the risks of severance before asserting a significant number of design patents directed to diverse products in a single ITC complaint.

³ Severance rules were raised but ultimately not applied in *Certain Earpiece Devices & Components Thereof*, Inv. No. 337-TA-1121 (which involved six patents and 32 claims across them) and in *Certain Data Transmission Devices, Components Thereof, Associated Software, & Prods. Containing the Same*, Inv. No. 337-TA-1150 (which involved three patents and 90 claims across them). In each investigation, the complainant and respondent opposed severance. The Commission Investigative Staff's reasons for recommending against severing Inv. No. 337-TA-1121 were two-fold: (1) there were only 12 independent claims asserted, and (2) five of the six asserted patents were in the same family and highly similar to one another. Rather than severing Inv. No. 337-TA-1150, the Commission reduced the asserted claims from 90 to 20 (total for all three asserted patents) and imposed other limitations to ensure that the investigation would progress efficiently.

Rule and Procedural Developments at the ITC in 2023

BY DANNY YONAN AND BROOKE MCLAIN

2023 was a calm year for the International Trade Commission (“ITC”) with no revisions to the USITC Rules & Procedures.¹ And while the number of Section 337 complaints filed experienced a three-year low, administrative law judges (“ALJs”) focused on fine tuning their rules and procedures and training new attorneys.

Complaints filed, OUII participation, & public interest. After the sharp increase in Section 337 complaints filed in 2021 and 2022, 2023 saw a slowdown in the number of Section 337 complaints filed. As of October 10, 2023, fifty-five Section 337 complaints and ancillary proceedings were filed in 2023. Although the Commission has not released the number of complaints and ancillary proceedings filed in the final quarter of 2023, the number will certainly be lower than the seventy-one complaints and ancillary proceedings filed in 2022 and eighty-two complaints and ancillary proceedings filed in 2021.² The decreased number of complaints and ancillary proceedings filed this year could be a return to normal—the average number of Section 337 complaints and ancillary proceedings filed per year for 2012-2022 is 62.18 filings per year—the number of complaints filed in 2021 and 2022 are statistical outliers. Or the decrease in Section 337 filings this year could be a reflection of the current legal market—clients may be hesitant to file an ITC proceeding in view of uncertain finances and a market featuring inflation and constant predictions about whether the economy is facing a recession.

Compared to the number of complaints filed, the number of investigations where an Office of Unfair Import Investigations (“OUII”) staff attorney was assigned did not change significantly. Staff attorneys are independent third-parties that help facilitate the

investigation, including discovery disputes. In 2022, a staff attorney was assigned in twenty-eight investigations.³ As of October 2023, a staff attorney was assigned in twenty-four cases. At present, there are nineteen investigative staff attorneys at the OUII.⁴

The decreased number of complaints also did not appear to impact the rate at which the Commission delegated public interest—consistent with previous years, public interest was delegated in less than a quarter of the investigations instituted. The Commission reports that in 2022 it assigned “the statutory public interest factors to the presiding ALJ in about 14 percent of total new investigations.”⁵ And in the first quarter of 2023,⁶ the ITC delegated public interest in two of eight investigations. The low percentage of public interest assignment is not favorable for Respondents as a finding that an exclusion order is not in the public interest can prevent the ITC from issuing an exclusion order even if the Commission finds a Section 337 violation.

The AAIA & NPEs.

In the past few years, certain Congress members have taken issue with how the Commission handles public interest, along with how the Commission evaluates the domestic industry prong and addresses non-practicing entities (“NPEs”). On May 18, 2023, U.S. Representative Schweikert (R-AZ) introduced H.R. 3535, the “Advancing America’s Interests Act” (“AAIA”) in the House of Representatives for the third time. The AAIA was previously introduced in the House of Representative in 2020 and again in 2021.

¹ “UTIC Rules of Practice and Procedure (337 Investigations) including updates through March 19, 2020”, USITC (Mar. 29, 2020), https://www.usitc.gov/sites/default/files/secretary/rules/337_investigations_2020-05767.pdf.

² As of October 10, 2023, 55 Section 337 complaints had been filed before the Commission compared to 71 complaints filed in 2022 and 82 complaints in 2021. See “Number of New, Completed, and Active Investigations by Fiscal Year (Updated Quarterly)”, USITC (Oct. 12, 2023), https://www.usitc.gov/intellectual_property/337_statistics_number_new_completed_and_active.htm.

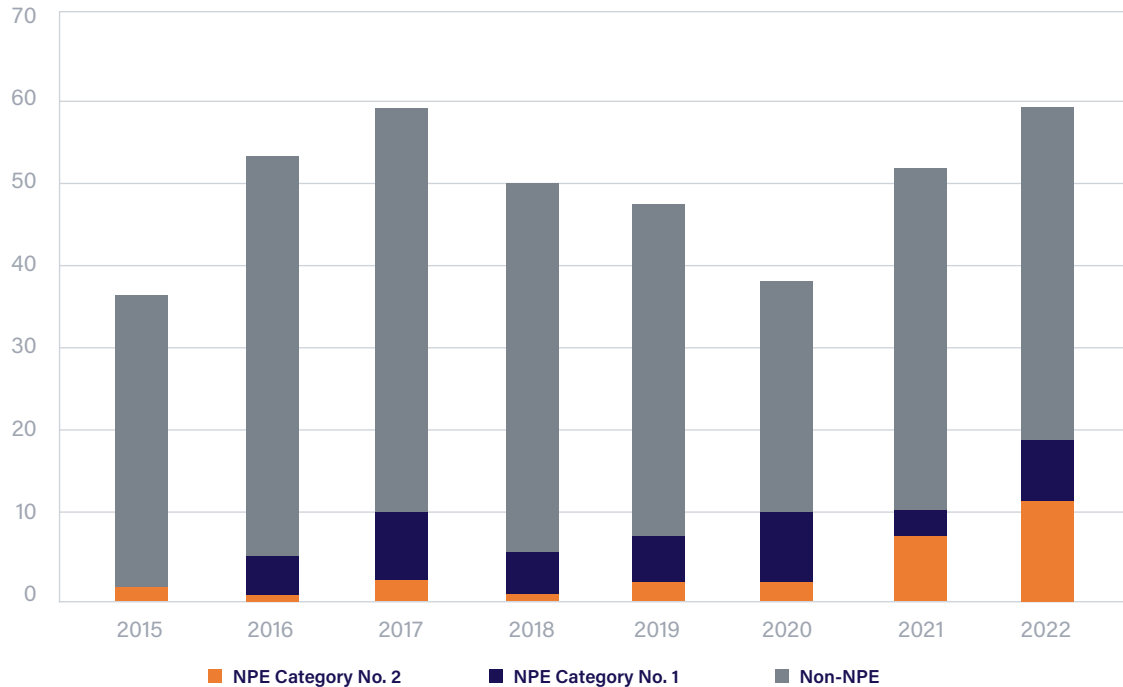
³ See “Search,” USITC, <https://ids.usitc.gov/search> (using “OUII Participation Level” field) (last accessed December 22, 2023).

⁴ “Staff Directory For the Office of Unfair Import Investigations,” USITC, https://www.usitc.gov/intellectual_property/contacts.htm (last accessed Dec. 23, 2023).

⁵ “Identification and Number of Cases Delegating Public Interest (Updated Quarterly)” USITC (Arp. 12, 2023), https://www.usitc.gov/337_stats_delegating_public_interest.

⁶ As of the publication of this article, the ITC has only released public interest data from the first quarter of 2023.

NPE Category Nos. 1 & 2 ITC Filings (2015-2022)



Confidential ©Sterne, Kessler, Goldstein & Fox P.L.L.C. 2023

The AAIA would reframe how the Commission addresses the domestic industry requirement and public interest. Specifically the bill proposes: (1) a Section 337 complainant may only rely on licensing activities that result in an actual product to satisfy the domestic industry prong; (2) a Section 337 complainant may only rely on licensing activities wherein the licensee affirmatively joins the Complaint; (3) the Commission must affirmatively determine that an exclusion order does not harm the “public interest” before issuance, and (4) the Commission must address whether potentially dispositive issues are appropriate for an early Initial Determination. Essentially, the proposed amendments are aimed at reducing NPE complaints by making it more difficult for NPEs to satisfy the domestic industry requirement and obtain an exclusionary order. The amendments also aim at protecting U.S. licensees from third-party subpoenas arising from 337 investigations and codifying the ITC’s existing “100-day early disposition program.” H.R. 3535 was referred to the House Committee on Ways and Means on the same day it was introduced in Congress.⁷ It is unlikely that H.R. 3535 will advance

past committee as both of the AAIA bills introduced in 2020⁸ and 2021⁹ stalled in committee after being introduced. The large majority of Congress does not appear to be interested in managing how the ITC handles Section 337 investigations.

Despite the AAIA’s likely fate, the AAIA highlights an ongoing ITC trend—NPE complainants are increasing at the ITC. The Commission divides NPEs into two categories. Category 1 NPEs are “inventors who may have conducted R&D or built prototypes but do not make a product covered by the asserted patents and therefore rely on licensing to meet the domestic industry requirement; research institutions, such as universities and laboratories, that do not make products covered by the patents, and therefore rely on licensing to meet the domestic industry requirement; start-ups that possess IP rights but do not yet manufacture products that practice the patent; and manufacturers whose own products do not

⁷ H.R.3535—118th Congress: Advancing America’s Interests Act,” Congress, <https://www.congress.gov/bill/118th-congress/house-bill/3535/committees?s=1&r=1&q=%7B%22search%22%3A%22H.R.+3535%22%7D&s=6&r=2> (last accessed Dec. 8, 2023).

⁸ H.R.5184—117th Congress: Advancing America’s Interests Act,” Congress, <https://www.congress.gov/bill/117th-congress/house-bill/5184/all-actions?q=%7B%22search%22%3A%22%5C%22Advancing+America%27s+Interests+Act%5C%22%22%7D&s=6&r=2> (last accessed Dec. 8, 2023).

⁹ H.R.8037—116th Congress: Advancing America’s Interests Act,” Congress, <https://www.congress.gov/bill/116th-congress/house-bill/8037/all-actions?q=%7B%22search%22%3A%22%5C%22Advancing+America%27s+Interests+Act%5C%22%22%7D&s=6&r=3> (last accessed Dec. 8, 2023).

Rule and Procedural Developments at the ITC in 2023

continued

practice the asserted patents.”¹⁰ Category 2 NPEs “do not manufacture products that practice the asserted patents and their business model primarily focuses on purchasing and asserting patents.”¹¹

The table on page 20 shows the number of Section 337 complaints filed by a NPE as reported by the ITC.¹² In 2022, 22.2% of Section 337 complaints were brought by a Category No. 2 NPE. This is a sharp increase from 2021 where Category No. 2 NPEs only brought 13.5% of the complaints.

Although the AAIA’s purpose is to target Category 2 NPEs complainants, the AAIA as it currently written would impact both Category Nos. 1 and 2 NPE complainants. If the AAIA ever gains traction, the Commission may choose to change how it evaluates public interest and the domestic industry prong to avoid broad legislation that impacts both patent pools and research institutions. However given the conservative nature of the Commission, this is unlikely to happen anytime soon.

Changes to ALJ Ground Rules.

Perhaps the biggest change at the ITC during 2023 were revisions to the ALJ’s ground rules. This is largely due in part to the fact that of four of the six current ITC ALJs were appointed in the past two years—ALJ Bhattacharyya was appointed in September 2021, Chief ALJ Cheney was appointed in February 2022, ALJ Moore was appointed in May 2022, and ALJ Hines was appointed February 2023. It is no surprise that one of the newer ALJs, ALJ Moore, revised his ground rules more than four times this year while ALJ McNamara, the most senior ALJ at the ITC,¹³ made no changes to her ground rules this year.

A quick summary of the changes each ALJ made to their ground rules is provided below.

- **ALJ Moore** revised Ground Rule 2.1 so that parties must now obtain judicial approval for an extension of time to respond to a subpoena. Several of ALJ Moore’s revisions focused on managing remote witnesses post-pandemic. ALJ Moore “disfavors” remote witnesses (see new Ground Rule 13.6.11) and parties must identify potential remote witnesses as part of their preliminary conference filings (see revised Ground Rule 3). ALJ Moore, like many in the legal field, is transitioning to Box and now requires discovery dispute letters be uploaded to Box (see revised Ground Rule 5.4.1.1). And Ground Rule 5.4.2.1 has been revised to warn parties that one means one—ALJ Moore added to his existing requirement that a party may only file one motion summary determination motion without leave the following language: “The parties should not attempt to circumvent this rule by addressing more than one issue in the motion.”

- **ALJ Cheney** added a footnote to Ground Rule 1.9.2 stating: “Questions or general correspondence should not be submitted to the email address Cheney1327@usitc.gov. Questions or correspondence sent to this mailbox will not be answered. See Ground Rule 15.” ALJ Cheney likely added this ground rule after parties sent general questions and correspondence to his email address instead of his staff’s email address.

- **ALJ Elliot** added Ground Rule 3.41.1, requiring parties arrange a telephone conference with the ALJ in an attempt to resolve discovery disputes before filing a motion. This change was likely made to avoid parties filing discovery motions and help facilitate discovery. As discussed further below, Ground Rule 16 was added to address the NEXT Advocates program. And Ground Rule 7 was revised to address supplemental

¹⁰ NPE Investigations, USITC (Feb. 15, 2023), https://www.usitc.gov/intellectual_property/337_statistics_number_section_337_investigations.htm.

¹¹ *Id.*

¹² NPE Investigations, USITC (Feb. 15, 2023), https://www.usitc.gov/intellectual_property/337_statistics_number_section_337_investigations.htm.

¹³ ALJ McNamara was appointed in August 2015 and ALJ Elliot was appointed in April 2019.

Rule and Procedural Developments at the ITC in 2023

expert reports—a party must seek leave to prepare and serve supplemental reports unless a supplemental report is already part of the procedural schedule.

- **ALJ Bhattacharyya** revised her ground rules to have parties submit an electronic copy of all demonstratives to Box within one business day of their use (see revised Ground Rule 9.5.7.1).

- **ALJ Hines** clarified how parties should send courtesy copies and request access to chambers' Box account."

NEXT Advocates Program.

All ALJs now endorse the NEXT Advocates program. "To ensure greater participation by less-experienced attorneys in the trial phase of section 337 proceedings," the ITC in 2022 announced its "Nurturing Excellence in Trial Advocates ("NEXT Advocates") program,¹⁴ modeled after the Patent and Trademark Office's LEAP Program. According to the Commission, ALJs are to: (1) address with counsel opportunities for less-experienced attorneys to participate in substantive oral arguments or to examine witnesses at the evidentiary hearing; (2) consider requests for oral arguments on substantive motions if a "substantive portion of such oral argument is presented by a less-experienced attorney;" and (3) "[p]ermit a more-experienced attorney to assist a less-experienced attorney, if necessary, and will permit a more-experienced attorney to clarify any statements on the record before the conclusion of the session, if necessary."

All ALJs now have a Ground Rule specifically addressing the NEXT Advocates program: ALJ McNamara's Ground Rule 11; ALJ Elliot's Ground Rule 16; ALJ Bhattacharyya's Ground Rule 14; and ALJ Moore's Ground Rule 15. These ground rules are identical, encouraging participation in the program and reiterating the requirements set by the Commission. ALJ Moore, ALJ Hines,

and ALJ Cheney's ground rules go beyond reiterating the Commission's requirements. ALJ Moore, and ALJ Hines's ground rules require that parties discuss participation in the program as part of the preliminary conference. And ALJ Cheney's ground rules require that parties discuss NEXT Advocate participation as part of an investigation's preliminary and pre-hearing conferences. (See Ground Rules 3(j) and 13.1).

In particular, it appears that ALJ Cheney actively encourages and discusses NEXT advocate participation during hearings with counsel, leading to greater participation in the program. For example, five NEXT advocates—three from complainants' side and two from respondents' side—participated in one trial.¹⁵

In addition to giving younger associates opportunities to participate in ongoing investigations, the ITCLA launched the Inaugural ITCLA Mock Hearing Program this year.¹⁶ For a \$250 fee, ITCLA members with three or fewer oral arguments or witness examinations in any federal tribunal could apply to participate in a mock hearing before ITC ALJs. Law firms were limited to two nominees and had to identify an experienced ITC practitioner to serve as coach for one team. (Not all nominated coaches were needed.) Participants were placed in teams of two to participate as Complainant and Respondent and took the direct and cross-examination of an expert witness provided by actual expert firms on October 12, 2023.

Participation in the NEXT Advocates program may increase as ALJs and law firms become more familiar with the program, similar to the increased participation seen in the PTO's LEAP program. Or participation may remain steady given the smaller number of Section 337 investigations as compared to PTAB proceedings and the reluctance to let junior attorneys argue in a forum where there's a risk of an exclusion order.

¹⁴ "NEXT Advocates: Nurturing Excellence in Trial Advocates," USITC, https://www.usitc.gov/next_advocates_nurturing_excellence_in_trial_advocates.htm (last accessed Dec. 8, 2023).

¹⁵ See *Hearing Tr., In re Certain Wet Dry Surface Cleaning Devices*, Inv. No. 337-TA-1304 (Dec. 9, 2022).

¹⁶ "2023 Mock Hearing Program," ITCLA, <https://itcla.org/events/EventDetails.aspx?id=1760002> (Last accessed Dec. 8, 2023).

Rule and Procedural Developments at the ITC in 2023

continued

Breaches of Protective Orders.

While rules and procedures may slightly change at the ITC, the ITC's concern for protecting confidential business information ("CBI") never changes. "Since 1991, the Commission has published annually a summary of its actions in response to violations of [protective orders] and rule violations."¹⁷ On December 1, 2023 the Commission released its annual "Summary of Commission Practice Relating to Administrative Protective Orders."¹⁸ The 2023 report addressed nine protective order ("PO") violations, providing a summary of the facts, the mitigating and aggravating factors, and the Commission's sanction. A large majority of the cases discussed by the Commission arose from an attorney publicly filing unredacted confidential business information ("CBI") on Electronic Document Information System ("EDIS"), the ITC's docketing system. The Commission issued private letters of reprimand or warning letters to the attorneys responsible for publicly disclosing CBI on EDIS.

The remaining PO violation examples provided by the Commission address improper retention of documents, breaches arising from email communication, and access to CBI information before a finalized cross-use agreement is in place.

In particular, the Commission discussed a case where multiple PO violations occurred when a law firm retained CBI documents past an investigation's termination date, an unauthorized attorney at the firm accessed an improperly retained document, used that document as a template in an unrelated section 337 investigation, and inadvertently disclosed CBI to opposing counsel in the unrelated investigation.¹⁹ The breach was discovered by the law firm who later destroyed CBI documents and confirmed that it did

not possess any other CBI from the terminated investigation. However, five years later the law firm discovered that it still had CBI documents from the terminated investigation in a misnamed archived folder that was inaccessible without permission.

The Commission issued a private letter of reprimand to the law firm because none of the individuals responsible for the breach still worked at the law firm when the Commission issued the sanction. The Commission further required that any of the PO signatories of the terminated investigation submit affidavits confirming the destruction of all CBI from the terminated investigation and confirming that the law firm had not retained CBI from any other terminated investigation.

In another case,²⁰ the Commission found a PO violation occurred where one attorney emailed draft documents containing CBI to an unauthorized recipient, who then shared the CBI with additional unauthorized individuals. The breach was discovered twenty days later, and the breaching parties self-reported to the Commission. The Commission issued a private letter of reprimand to the attorney who emailed the CBI and warning letters to the attorneys copied on the breach email who failed to identify the breach because as PO signatories, "they had an opportunity to immediately discover" the breach and "prevent the second breach from occurring."²¹

In another case²² the Commission found three PO violations occurred where the parties had not finalized a cross-use agreement to use CBI information in a related district court case. The attorneys provided CBI to an associate attorney who was not PO signatory—and not familiar with ITC practices. The parties also sought permission from opposing counsel to use a CBI exhibit in the district court case. Opposing counsel denied the request and the attorneys instructed

17 "Summary of Commission Practice Relating to Administrative Protective Orders," at 9-17 (Dec. 1, 2023), https://www.usitc.gov/sites/default/files/secretary/fed_reg_notices/rules/apo_notice12012023sgl.pdf.

18 *Id.* at 1.

19 *Id.* at 10-11.

20 *Id.* at 11-12.

21 *Id.* at 12.

22 *Id.* at 14-16.

Rule and Procedural Developments at the ITC in 2023

the associate to remove the CBI exhibit from the filing. The associate instructed the paralegals to remove the CBI exhibit but did not confirm that the CBI exhibit had actually been removed from the filing. The CBI exhibit was subsequently filed on the district court's electronic case-filing system, PACER.

The Commission issued private letters of reprimand to the partner who served as lead counsel and senior counsel as both were part of the decision to use the CBI in the district court filing and provided the CBI to the associate attorney and delegated removing the exhibit to the associate. The Commission issued a warning letter to another partner who worked on the district court filing, was aware of the associate's access to CBI, but was not involved in finalizing the filing.

The report and the cases discussed above are good practice reminders for clients and attorneys to always be cognizant of what information is CBI and who has access to it. Attorneys should always check whether any filing contains CBI before uploading to EDIS and monitor the email recipients of an email containing CBI. Clients should alert counsel if they have a belief they were inadvertently sent CBI of the opposing party. And parties should timely negotiate cross-use agreements to prevent inadvertent disclosure in related proceedings.

* * *

Although 2023 did not see any major changes at the Commission level, that may be in-part because of the lower number of Complaints filed. Despite the AAILA bill being introduced to Congress for the third time, the Commission does not appear to be interested in addressing the rising number of Category No. 2 NPE complainants or increase the rate at which they delegate public interest. 2024 may be a more interesting year at the ITC as newer ALJs settle into their position, gain experience, and further revise their ground rules and procedures.

It's Easy to Subscribe to Sterne Kessler's Content!

Visit us online to receive client alerts, newsletters, webinar invitations, event notifications, and other intellectual property updates from our experts.



We're Hiring!



Our practitioners include patent and trademark prosecutors, litigators, and appellate attorneys, as well as scientists and engineers working as patent agents and technical specialists. Our team collaborates in a diverse and vibrant culture. Consider joining us!

Scan the QR code above to learn more about career opportunities and firm culture at Sterne Kessler.

About Our ITC Practice

The U.S. International Trade Commission (ITC) is a popular and effective forum for high-stakes, global disputes involving products imported into the United States. Investigations are complex and fast-paced, and the potential outcome can have serious consequences for a global business. With one of the nation's top ITC practices, Sterne Kessler offers unrivaled experience, comprehensive litigation strategy, and the legal and technical know-how to achieve the best possible results for our clients.

In the last five years, Sterne Kessler has handled more cases at the ITC than 85% of firms appearing before the Commission. We excel at handling the complexities of a Section 337 case due to our solid foundation of IP trial and technology experience, our deep understanding of administrative law, and the ITC's unique rules and procedures. Our attorneys have successfully litigated nearly 50 investigations for clients that include Volkswagen, Wirtgen, and BTL Industries, amongst others.

Sterne Kessler's technical bench is an unparalleled strategic advantage—we leverage our team of 100+ advanced degrees, including 60+ Ph.D.s., in science and engineering disciplines to grasp complex technologies quickly. We effectively explain complex technology and IP concepts to judges in a compelling way that increases the likelihood of a successful outcome.

We have experience representing both complainants and respondents in Section 337 investigations, and a hallmark of our practice is our client service and ability to mobilize powerful teams at the outset of a case to identify issues and help you navigate discovery demands efficiently and cost-effectively. We also help clients facing a potential exclusion order to redesign their products so they can continue to be imported and sold in the United States. Our teams are led by highly regarded trial lawyers and staffed by technically trained IP lawyers to tailor a strategy to best position your company at the ITC and in parallel proceedings at the Patent Trial and Appeal Board or in U.S. District Courts.

Whether asserting your patents or defending your products before the ITC, our team of experienced litigators and patent attorneys can help you manage these complex, fast-moving investigations and achieve the most favorable outcome for your business.

Please visit our website to learn more about the firm and our practice.



Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

1101 K Street NW, 10th Floor, Washington DC 20005 • 202 371-2600 • sternekessler.com