



Hogan Lovells: ITC Section 337 quarterly highlights

27 June 2018

Recent developments and practice tips from the U.S. International Trade Commission (ITC) bench by Judge Theodore R. Essex

Comments on the new ITC rules for practice and procedure:

The International Trade Commission has amended its rules of practice and procedure (19 C.F.R. Parts 201 and 210) concerning rules of general application, adjudication, and enforcement. See 83 Fed. Reg. 21140-64 (8 May 2018); *see also* Hogan Lovells LimeGreen IP News, "[ITC: Commission Amends Rules of Practice and Procedure](#)" (21 May 2018). The effective date of the changes is 7 June 2018, and shall apply to investigations instituted subsequent to that date. The final regulations contain the 11 changes from the proposals in the Notice of Proposed Rule Making (NPRM) (80 Fed. Reg. 57553-64 (Sept. 24, 2015)). The 11 changes are summarized below followed by my comments.

1. With regard to new Rule 201.16(f) relating to electronic service by the parties, the commission has determined that the administrative law judge (ALJ) may indicate by order what means are acceptable to ensure documents to be served are securely stored and transmitted by the serving party in a manner that prevents unauthorized access and/or receipt by anyone not authorized to view specified confidential business information.
2. With regard to new Rule 210.10(a)(6), the commission will have the ability to institute multiple investigations from a single complaint, rather than instituting one investigation that may be too cumbersome for efficient adjudication by the commission or an ALJ.
3. The commission has determined to amend proposed Rule 210.10(b)(1) to clarify that the notice of investigation will define the scope of the investigation in plain language so as to make explicit what the accused products or category of accused products will be the subject of the investigation, in accordance with Rule 210.12(a)(12), which governs the contents of the complaint.
4. The commission has determined to amend proposed Rule 210.10(b)(3) to clarify that an initial determination ruling on a potentially dispositive issue in a 100 day proceeding is due within 100 days of institution of an investigation so designated. The rule is also amended to clarify that the presiding ALJ is authorized, in accordance with Rule 210.36,

to hold expedited hearings on any such designated issue and will also have discretion to stay discovery of any remaining issues during the pendency of the 100 day proceeding.

5. The commission has determined to amend proposed Rule 210.14(h) to clarify that an ALJ may sever an investigation into two or more investigations at any time prior to or upon 30 days from institution of the investigation. The rule will also clarify that severance may be based upon a motion from any party. The judge's decision will be in the form of an order. The newly severed investigations shall remain with the same presiding ALJ unless the severed investigation is reassigned at the discretion of the chief ALJ.
6. The commission has determined that ALJs will not be able, under Rule 210.14(i), to designate potentially dispositive issues for inclusion in a 100 day proceeding following institution of an investigation. Proposed Rule 210.14(i), including all references to this rule, will not be in the final rules.
7. The commission has determined to amend proposed Rule 210.15 to clarify that the rule is intended to prohibit the filing of any motions before the commission during preinstitution proceedings except with respect to motions for temporary relief filed under Rule 210.53.
8. Because the commission has determined that ALJs will not be able to designate potentially dispositive issues for inclusion in a 100 day proceeding following institution of an investigation, proposed Rule 210.22 that allows parties to file a request for such designation by motion will not appear in the final rules.
9. The commission has determined to amend proposed Rule 210.32(d)(1) to clarify that a party may serve subpoena objections within the later of 10 days after receipt of the subpoena or within such time as the ALJ may allow. In addition, the proposed rule is amended to clarify that if an objection is made, the party that requested the subpoena may move for a request for judicial enforcement upon reasonable notice to the other parties or as otherwise provided by the ALJ who issued the subpoena. Similarly, the commission has determined to amend proposed Rule 210.32(d)(2) to clarify that a party may file a motion to quash a subpoena within the later of 10 days after receipt of the subpoena or within such time as the ALJ may allow.
10. The commission has determined to add Rule 210.42(h)(7) to specify that an initial determination issued pursuant to proposed Rule 210.42 (a)(3) will become the commission's final determination 30 days after issuance, absent review.
11. The commission has determined to amend proposed Rule 210.43(a)(1) to clarify that petitions for review of an initial determination ruling on a potentially dispositive issue must be filed within five business days after service of the initial determination. The commission has also determined to amend proposed Rule 210.43(c) to clarify that the time for filing responses to petitions for review is five business days.

Commentary:

The proposed rules would have provided greater flexibility and authority to be vested in the ALJ regarding the 100 day proceeding. For example, proposed Rule 6, not adopted by the commission, would have allowed the ALJ to designate issues for the 100 day proceeding. Proposed Rule 8, not adopted by the commission, would have allowed the parties to propose to the ALJ an issue for the 100 day program. The new rules maintain authority for designating issues for a 100 day proceeding to the commission.

In view of the foregoing, it is unclear what, if any, difference the new rules will make with regard to this seldom used procedure. Since 2013, there have been only eight cases so designated for the single issue treatment (including a case (*Recombinant Human Erythropoietin*, Inv. No. 337-TA-568) brought as a 100 day single issue case prior to the pilot program). Of the cases brought, several were found to not be resolved, and went on to a full hearing, so the program has not yet brought the savings of time and money that was hoped for. Moreover, the commission had previously not allowed judges to delay discovery in other aspects of a case designated for the 100 day program, so that the disposition, if not favorable to the single issue, would not be delayed by the single issue program. By allowing the judges to suspend discovery, any savings in time may also not be realized.

Amended Rule 201.16(f) allows the ALJ to set the acceptable means for electronic service by the parties, to ensure documents to be served are securely stored and transmitted in a manner to prevent unauthorized access by those not permitted to view confidential information. While this is a matter for the parties to consider in advance, it should have little if any impact on the practice at the ITC.

With respect to new Rule 210.10(a)(6) that allows the ITC to institute multiple investigations based on one complaint, the commission removed the proposed stated criteria by which the commission may determine when to institute multiple investigations from a single complaint, substituting the single criteria "the consideration of efficient adjudication." The commission has for a considerable time been concerned with two factors that seem to have driven this rule, first, meeting target dates and processing times. When the commission in the past has accepted complaints citing multiple patent families in unrelated fields, the difficulties in discovery, witnesses, and processing cases have impacted the ability of the ALJs and commission to meet target dates. The commission has also been concerned that when cases contained multiple patent families, patents, and claims, those who monitor the commission's work would not understand how much the commission was actually doing, because one case before the ITC would be the equivalent of several in district courts. By allowing the commission to sever cases and give each one a new number, the commission clearly aimed to more accurately reflect the work performed by the ALJs and commission.

The same reasoning applies to new Rule 210.14(i) permitting the ALJs to use their discretion to sever an investigation into two or more investigations within 30 days of institution. Severing large investigations will ensure they proceed to completion according to the Section 337 timelines and help ALJs better manage their dockets. ALJs may be more likely to sever cases with multiple parties and/or multiple patents. For example, where one party is only involved in a subset of the issues, the ALJ may serve the investigation for efficiency.

The commission has determined to amend proposed Rule 210.10(b)(1) to clarify that the notice of investigation will define the scope of the investigation in plain language so as to make explicit what the accused products or category of accused products will be the subject of the investigation in accordance with Rule 210.12(a)(12), which governs the contents of the complaint. While this rule change will not have a great impact on the conduct of the hearings with the ALJs, or the appeal within the ITC, the parties will have to pay close attention to what is included in the complaint if they are to succeed in the enforcement stage should the complainant prevail. Failure to carefully monitor all the products or articles that should be excluded as a result of a commission order could be very harmful to the successful complainant, resulting in pyrrhic victories unlikely to please clients.

New Rule 210.32(e) clarifies subpoena practice and brings the ITC's subpoena practice in closer conformity with the Federal Rules of Civil Procedure. The amendments provide that a party upon

which a subpoena has been served may file an objection to the subpoena or motion to quash within 10 days of receipt of the subpoena or as the ALJ may provide. In particular, the ITC sought to capture the burden shifting of the Federal Rules of Civil Procedure such that when a subpoenaed entity files an objection, the burden shifts to the requesting party, requiring the requester to file for relief. The ITC's purpose was to require the requesting party to prove that information it seeks from the subpoenaed party is relevant and not burdensome. The amendments clarify that after an objection is made and negotiations fail, the requesting party must provide notice before seeking judicial enforcement. The ITC noted that the ALJ may potentially require that the parties meet and confer prior to the filing of a request for judicial enforcement.

New Rule 210.15 prohibits filing motions before the commission during preinstitution proceedings. While this seems to codify common sense, in several recent matters the commission seemed to be hearing substantive matters through motion practice before it had determined to conduct an investigation. Neither the statute (19 U.S.C. § 1337) nor the rules provide for this practice, and the validity of commission actions taken without opening a matter is questionable. It is hoped this regulation will put a rest to such preinstitution practices.

Commission finds no violation in *UV Cable Coatings For Optical Fibers*, Inv. No. 337-TA-1031 and that asserted patent claims are invalid for lack of written description

On 8 May 2018, the commission issued its [notice of final determination](#) in *UV Cable Coatings for Optical Fibers, Coated Optical Fibers, and Products Containing Same*, Inv. No. 337-TA-1031 finding no violation. The initial determination (ID) had found that only one of the three respondents was in violation for infringement of two of the three patents, directed to coating compositions for optical fibers in cables, asserted at the hearing, specifically claim 21 of the asserted '508 patent and claims 1-10 and 13-15 of the asserted '103 patent. However, after review, the commission reversed the ID's conclusion that those claims are not invalid for lack of written description. The public version of the [commission opinion](#) issued on 7 June 2018 found that the asserted claims of the '508 and '103 patents include overly broad compositional limitations that fail to place any meaningful limit on the scope of the claims. The commission also found that the simultaneous presence of each of the claimed physical property limitations was unpredictable and that the patent specification provides little in the way of supporting disclosure, including working examples. In view of the foregoing, the commission held "[t]his unpredictability, together with the exceedingly broad scope of the claims and the limited disclosure in the specification supports a finding that the patents fail to convey possession of the full scope of the claimed invention." The commission also affirmed the ID's determination that additional claims 1-8, 11, 15, and 18-19 of the '508 patent and claim 30 of the additional asserted '659 patent are invalid for lack of written description based on modified reasoning.

In *Certain Graphics Systems, Components Thereof, and Consumer Products Containing the Same*, Inv. No. 337-TA-1044, Judge McNamara issues an ID finding violation of Section 337

On 13 April 2018, ALJ McNamara issued an [initial determination](#) finding a violation of Section 337 in *Certain Graphics Systems, Components Thereof, and Consumer Products Containing the Same*, Inv. No. 337-TA-1044. On 24 January 2017, Advanced Micro Devices, Inc. (AMD) and ATI Technologies, ULC (ATI) filed a complaint alleging that LG Electronics, Inc., LG Electronics, U.S.A., Inc., and LG Electronics MobileComm U.S.A. (collectively, LG); VIZIO, Inc. (VIZIO); MediaTek Inc. and MediaTek U.S.A., Inc. (collectively, MediaTek); and Sigma Designs Inc. (SDI) were importing into the United States products infringing U.S. Patents Nos. 7,633,506, 7,796,133, and 8,760,454, directed to graphics processors employing unified shaders. The commission instituted the investigation on 17 March 2017. LG and AMD reached an agreement to terminate

the investigation in October 2017, and as a result, the initial determination addressed only the claims against VIZIO, MediaTek, and SDI under the '506 and '133 patents. The accused products were divided into two categories: singlepipe products and multipipe products. ALJ McNamara determined that none of the singlepipe products infringed the asserted claims of the '133 patent, but that all of the multipipe products infringed the asserted claims of the '506 patent. All of the respondents' invalidity arguments were rejected.

ALJ McNamara recommended issuance of a Limited Exclusion Order (LEO) with a certification provision against VIZIO, MediaTek, and SDI, rejecting VIZIO's argument under *Certain Erasable Programmable Read-Only Memories, Components Thereof Products Containing Such Memories, and Processes for Making Such Memories*, Inv. No. 337-TA-276 (EPROMs) that its television products were "downstream" products that were entitled to exemption from the LEO. ALJ McNamara determined that the VIZIO televisions were not downstream products within the meaning of EPROMs—i.e., "products which were not themselves the subject of a finding of violation"—pointing out that the LEO is "limited to only those VIZIO products that are specifically accused in this investigation, and are imported and sold by VIZIO." ALJ McNamara further recommended issuance of a cease and desist order CDO against VIZIO and SDI in light of their maintenance of "commercially significant inventories of infringing products within the United States" and denial of the complainants bond request, citing the lack of competition between the complainants' and respondents' products.

In *Certain Non-Volatile Memory Devices and Products Containing the Same*, 337-TA-1046, Judge Lord finds most asserted claims not-infringed or invalid as obvious

On 27 April 2018, Judge Dee Lord issued an [initial determination](#) (ID) in *Certain Non-Volatile Memory Devices and Products Containing the Same*, 337-TA-1046, finding two of three patents not infringed and the majority of asserted claims of the third patent invalid as obvious. Judge Lord further found that complainants Macronix International Co., Ltd. and Macronix America, Inc. (collectively, Macronix) had not shown that a domestic industry exists or is in the process of being established in the United States. Respondents, complainants, and the Office of Unfair Import Investigations have all filed petitions for review of certain aspects of the ID, which are pending before the commission.

Macronix filed a complaint on 7 March 2017 alleging that multiple Toshiba entities infringe certain claims of U.S. Patent Nos. 6,552,360 (the '360 Patent), 6,788,602 (the '602 Patent), and 8,035,417 (the '417 Patent) directed to the structure and operation of non-volatile memory devices.

In the ID, Judge Lord found Toshiba did not infringe the asserted claims of the '360 and '417 Patents, but that certain accused Toshiba products infringe claims 1-10 of the '602 Patent. However, Judge Lord also found that claims 1-5 and 7-10 of the '602 Patent were invalid as being obvious. Thus, claim 6 of the '602 Patent was the only asserted claim found to be infringed while not being rendered obvious by the prior art. In addition, Judge Lord found that Macronix had not shown the existence of a domestic industry in the U.S. with respect to the asserted patents, and that Macronix had not shown that a domestic industry was in the process of being established. In particular, Judge Lord rejected Macronix's arguments that Section 337(a)(2) permits a company to establish a domestic industry based on research expenditures only, without needing to relate those research expenditures to an actual article commerce that practices the asserted patent(s), instead finding that Section 337(a)(2) cannot be read to protect research not embodied in such an article of commerce.

In *Solid State Storage Drives, Stacked Electronic Components, and Products Containing Same*, 337-TA-1097, Judge Lord issues early ID in 100 day proceeding finding economic prong of domestic industry satisfied for three asserted patents and terminating investigation as to one asserted patent

On 26 January 2018, the commission issued a [notice](#) instituting *Solid State Storage Drives, Stacked Electronic Components, and Products Containing Same*, 337-TA-1097, to determine whether there is a violation of Section 337 with respect to the importation into the U.S. of certain solid state storage drives, stacked electronic components, and products containing same by reason of infringement of four asserted patents. The commission instructed that the presiding administrative law judge hold an early evidentiary hearing and issue an initial determination within 100 days of institution, subject to the grant of a limited extension by the ALJ for good cause shown, to determine whether the economic prong of domestic industry has been satisfied for each asserted patent. This is the seventh time the commission has instructed an ALJ to undertake a 100 day ID procedure. ALJ Dee Lord assigned to this investigation issued [Order No. 3: Setting Target Date; 100-Day Procedural Schedule](#) limiting discovery during the first 100 days to the issue of economic prong of domestic industry, including requiring the parties to make certain mandatory disclosures relating to this issue, and, *inter alia*, setting a 100 day initial determination due date and early target date. On 11 May 2018, Judge Lord issued an unpublished ID finding substantiation of the economic prong of domestic industry for three of the asserted patents and terminating the investigation as to one asserted patent. Following issuance of the ID, limited petitions for review were filed by respondents and staff, and Judge Lord extended the target date for completion of the investigation and revised the procedural schedule for the three asserted patents. On 12 June 2018, the commission determined to review the subject ID, and on 20 June 2018 issued a notice of its decision affirming with modification the subject ID finding complainant has satisfied the economic prong of the domestic industry requirement for all but one of the asserted patents.

Commission institutes 100 day ID procedure in *Clidinium Bromide and Products Containing Same*, 337-TA-1109 and notice triggers dispute by parties over scope of 100 day proceeding

On 23 April 2018, the commission issued a [notice](#) instituting *Clidinium Bromide and Products Containing Same*, 337-TA-1109 to determine whether there is a violation of Section 337 with respect to the importation into the United States of certain clidinium bromide and products containing same by reason of false advertising and unfair competition under the Lanham Act, the threat or effect of which is to destroy or substantially injure an industry in the United States. Just prior to institution of the investigation, by letter of 18 April 2018, the commission advised complainants' counsel that the commission determined not to institute an investigation based on paragraphs 74 through 82 of the amended complaint alleging a violation of Section 337 based on the standards of the Food, Drug, and Cosmetic Act (FDCA), over which the commission does not have jurisdiction. However, the commission advised that it has determined to institute based on the amended complaint's Lanham Act allegations in paragraphs 37 through 73, which relate to representations with respect to FDA approval status, that are not precluded by the FDCA. In the notice, the commission instructed that the presiding administrative law judge hold an early evidentiary hearing and issue an initial determination within 100 days of institution, subject to the grant of an extension of up to 50 days (the longest such extension ever acknowledged by the commission) by the ALJ for good cause shown, to determine "whether the complainants have demonstrated an injury or threat of injury to an industry in the United States." This is the eighth time the commission has instructed an ALJ to undertake a 100 day ID procedure, but the first time the commission's notice triggered a dispute by the parties over the proper scope of the 100 day proceeding. Specifically, at the Case Management Conference on 3 May 2018, complainants

and staff asserted that the scope is two separate prongs: (1) the injury or threat of injury but not involving whether the false advertising and unfair competition causes such injury; and (2) whether complainants have a domestic industry in the United States. In a brief filed on 8 May 2018, respondents asserted that the 100 day proceeding should be limited to complainants' "alleged domestic industry and whether such domestic industry is of the type and scale any harm to which would constitute a cognizable, substantial injury." In a joint submission filed on 8 May 2018, the parties requested a ruling by 9 May on the scope of the 100 day proceeding. At the Case Management Conference, Administrative Law Judge Thomas Pender stayed discovery of the false advertising and unfair competition issues pending the 100 day proceeding and issued Order No. 7: Final Procedural Schedule For Early Decision Proceedings on 17 May 2018 setting, *inter alia*, a hearing date on 9-10 July 2018 and deadline for ID on 20 September 2018.

Amarin's omega-3 fatty acid appeal – Update from oral argument at the Federal Circuit

In previous editions of our ITC Section 337 Quarterly Highlights, we have followed the progress of Amarin's complaint regarding the importation of synthetically produced omega-3 products. The Federal Circuit heard oral arguments in Amarin's appeal on 8 June. Counsel for Amarin faced off with representatives from the ITC, intervenors, and the U.S. government. The panel consisted of Chief Judge Prost, Judge Wallach, and Judge Hughes.

Amarin filed its complaint on 30 August 2017 (ITC Docket No. 3247) alleging unlawful importation of synthetically produced omega-3 products. Amarin claimed that the omega-3 products are falsely labeled and/or advertised as "dietary supplements" under both the Lanham Act and the Food, Drug, and Cosmetic Act (FDCA). The commission decided not to institute an investigation because it lacked jurisdiction. It found that the Lanham Act claims were precluded by the FDCA and that the Food and Drug Administration (FDA) is charged with administering the FDCA. Amarin appealed this decision to the Federal Circuit.

In the oral argument, Amarin argued that the court had jurisdiction (1) under the statute, (2) under the APA, or (3) based upon its mandamus jurisdiction under the All Writs Act. The ITC actually agreed that Amarin had mandamus jurisdiction, but the intervenors disagreed and Chief Judge Prost appeared receptive to the intervenors' position. Amarin argued that the statute's "shall investigate" language was mandatory and that the ITC must institute an investigation unless the complaint is procedurally defective. They argued that, in addition to any action that could be taken by the FDA, the ITC had jurisdiction. Intervenors argued that when the entire statutory provision is considered, "shall" really means "may." Chief Judge Prost seemed skeptical of this interpretation. Overall, the court was concerned that they did not have a properly reviewable "final determination" of the ITC before them. Judge Hughes appeared concerned that if the Federal Circuit did not have jurisdiction, which judicial forum did? He noted the strong preference for judicial review of agency actions and suggested that this basic legal question was not one that Congress had deemed unreviewable.

The U.S. government only addressed the question of preemption. It argued that an FDCA violation cannot be enforced through the ITC. According to the government, only the FDA has the legal and technical expertise needed to determine if a product is a nutritional supplement or a new drug. The court sought clarity from the government on whether the FDA planned to issue any guidance that might answer the fundamental question raised by Amarin (are the products at issue mislabeled under the FDCA?). The government indicated that it was not aware of any forthcoming guidance that would answer this question. We shall keep you apprised of the Federal Circuit's decision in this case.

Federal Circuit stays briefing of Razor's 337-TA-1000 appeal pending commission's motion to dismiss

On 8 May 2018, the International Trade Commission filed a [Motion to dismiss](#) Razor USA LLC, Inventist, Inc., and Shane Chen's appeal (Case No. 2017-2591) of the commission's final determination in *Certain Motorized Self-Balancing Vehicles*, 337-TA-1000. In its motion, the commission argued that the appeal will be rendered moot when the reissue application for the patent at issue is granted. The commission noted that the reissue application was recently allowed by the U.S. Patent and Trademark Office (USPTO), and, although the reissue patent has not yet been issued, the patentee affirmatively indicated intent to pay the reissue fee. The commission argued that because the allowed claims of the reissue patent and the claims of the original patent at issue in the appeal are not "substantively identical" under 35 U.S.C. § 252, the appeal will be moot.

In its motion to dismiss, the commission also sought a stay of the appeal pending the motion's resolution: "The Commission understands that pursuant to Fed. Cir. Rule 31(c), this motion suspends further proceedings in this appeal pending its disposition. If this understanding is not correct, the Commission requests that the appeal be stayed pending resolution of this motion and that its request for a stay be given expedited treatment." Hangzhou Chic Intelligent Technology Co., Ltd., one of the intervenors in the appeal, agreed with the commission's motion to dismiss, but filed a [cross-motion](#), seeking that the stay be entered "until the latter of the suspended briefing deadline under Federal Circuit Rule 31(c), or 14 days after the issuance of the reissue patent." On 15 May 2018, the Court of Appeals for the Federal Circuit issued an [order](#) noting that the briefing schedule for the appeal was stayed pursuant to Fed. Cir. Rule 31(c) and would remain stayed pending resolution of the commission's motion. We shall keep you apprised of the Federal Circuit's decision in this case.

Upcoming ITC Trial Lawyers Association events

In its continuing outreach program, the ITC Trial Lawyers Association (ITCTLA) will hold a conference introducing ITC Section 337 investigations on 29 June 2018 at Venable, LLP, 101 California Street, Suite 3800, San Francisco, CA 94111. A brown bag lunch for new ITC Judge Clark S. Cheney will be held in on 10 October 2018 at Covington & Burling LLP, 850 10th Street NW, Washington, DC 20001. The fall meeting and dinner for the ITCTLA will be held on 15 November 2018. Further details will be provided closer to the date for this event.

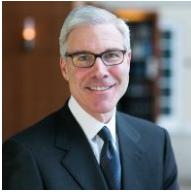
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