

**United States Court of Appeals
for the Federal Circuit**

ALIGN TECHNOLOGY, INC.,
Appellant,

v.

INTERNATIONAL TRADE COMMISSION,
Appellee,

AND

CLEARCORRECT OPERATING, LLC,
Intervenor,

AND

**CLEARCORRECT PAKISTAN (Private), LTD., MR.
MUDASSAR RATHORE, DR. WAQAS WAHAB, DR.
NADEEM ARIF, AND DR. ASIM WAHEED,**
Intervenors.

2013-1240, -1363

Appeals from the United States International Trade
Commission in Investigation No. 337-TA-562.

Decided: July 18, 2014

IGOR V. TIMOFEYEV, Paul Hastings LLP, of Washington, DC, argued for appellant. With him on the brief were STEPHEN B. KINNAIRD, and THOMAS A. COUNTS, of San Francisco, California.

JAMES A. WORTH, Attorney, Office of General Counsel, United States International Trade Commission, of Washington, DC, argued for appellee. With him on the brief were DOMINIC L. BIANCHI, General Counsel, and WAYNE W. HERRINGTON, Assistant General Counsel.

MICHAEL D. MYERS, McClanahan Myers Espey, LLP, of Houston, Texas, argued for intervenors. With him on the brief for ClearCorrect Operating, LLC were RANDY MCCLANAHAN and ROBERT H. ESPEY, II. Of counsel on the brief was GARY M. HNATH, Mayer Brown LLP, of Washington, DC. On the brief for ClearCorrect Pakistan (Private), Ltd., et al, were LEI MEI and REECE NIENSTADT, Mei & Mark LLP, of Washington, DC.

Before PROST, *Chief Judge*, and CHEN, *Circuit Judge*.*

CHEN, *Circuit Judge*.

The International Trade Commission's regulations authorize the Commission to review a decision of an administrative law judge (ALJ) when that decision is designated as an "initial determination." Other ALJ decisions, such as an "order," are not reviewable. Here, the ALJ denied a motion via an order. This case requires us to consider whether the Commission's review of that order was procedurally sound. For the reasons set forth below, we hold that it was not.

* Randall R. Rader, who retired from the position of Circuit Judge on June 30, 2014, did not participate in this decision.

I. BACKGROUND

This case arises out of a proceeding before the Commission to enforce a Consent Order entered into by Align Technology, Inc. (Align), the complainant of an original, underlying investigation, and respondents to that investigation, OrthoClear, Inc., OrthoClear Holdings, Inc., and OrthoClear Pakistan Pvt, Ltd. (collectively, OrthoClear).

Align develops, manufactures, and markets clear aligners to treat malocclusion—i.e., teeth misalignment. Conventionally, dental professionals treated misalignment with metal archwires and brackets, commonly known as braces. Braces, however, have a number of disadvantages, including tooth discoloration, oral discomfort, and, for some, embarrassment.

To overcome these problems, Align conceived of and developed its clear aligners, marketed as the Invisalign System. The Invisalign System, which is based on Align's patented technology, uses a series of clear dental aligners—"incremental positioning adjustment appliances"—that are worn sequentially over a fixed time period to adjust the position of a patient's teeth. Because each patient's teeth are unique, the aligners must be custom-designed. To design these aligners, dental professionals generate and obtain data to determine the positioning of a patient's teeth and create complex three-dimensional digital models of each incremental configuration for each aligner. The three-dimensional digital model of each configuration is manipulated to create a "digital data set," which is used to manufacture a series of successive aligners to be worn by a patient that incrementally move the teeth to the desired alignment. In general, Align's asserted patents are directed to various methods and orthodontic treatment plans using these digital data sets.

In 2005, Align's founder and former Chief Executive Officer, Muhammad Chisti, founded OrthoClear and used former Align employees in Pakistan and the United

States to manufacture and sell dental aligners. Believing OrthoClear to be infringing its patents and using its trade secrets, Align filed a complaint with the Commission in 2006 (hereinafter, the underlying investigation).

A. The Underlying Investigation

Align's complaint alleged that OrthoClear violated 19 U.S.C. § 1337 by importing, selling for importation, or selling within the United States after importation aligners that infringe Align's asserted patents,¹ and also by misappropriating Align's trade secrets. Notice of Investigation, 71 Fed. Reg. 7995, 7995–96 (Feb. 15, 2006).

In August 2006, OrthoClear negotiated a global settlement with Align that required OrthoClear to assign its entire intellectual property portfolio to Align, to agree to entry of the Consent Order, and to file a joint motion to terminate the investigation. The ALJ granted the joint motion, and the Commission entered the Consent Order and terminated the underlying investigation. *See Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same*, Inv. No. 337-TA-562, 2006 WL 3462199 (U.S.I.T.C. Nov. 13, 2006).

The Consent Order provided, in relevant part:

The incremental dental positioning adjustment appliances manufactured by or for OrthoClear referenced in the complaint and any other articles manufactured in violation of the patents or trade secrets described therein (the "Articles") are hereby prohibited from importation into the United States until the expiration of the last to expire of the following patents . . . U.S. Patent No.

¹ U.S. Patent Nos. 6,685,469; 6,450,807; 6,394,801; 6,398,548; 6,722,880; 6,629,840; 6,699,037; 6,318,994; 6,729,876; 6,602,070; 6,471,511; and 6,227,850.

6,722,880 (“the ’880 patent”) [and] U.S. Patent No. 6,471,511 (“the ’511 patent”) . . . , except under license of the patent owner or as provided by law.

J.A. 69; *id.* at 7974–75 ¶ 2. The Consent Order also included successor and aiding-and-abetting provisions that extended the importation prohibition beyond OrthoClear. *See* J.A. 7675 ¶ 2 (mandating that OrthoClear shall not “knowingly aid, abet, encourage, participate in, or induce the sale for importation into the United States or sale in the United States after importation of the Articles”); *id.* ¶ 3 (providing that the Consent Order “shall be applicable and binding upon OrthoClear, its officers, directors, agents, servants, employees, successors and assigns, and all persons, firms, or corporations acting or claiming to act on its behalf or under its direction or authority”).

B. The Enforcement Proceeding

After suspecting that OrthoClear and others were violating the Consent Order, Align filed a new complaint, this time for an enforcement proceeding under 19 C.F.R. § 210.75 (hereinafter, the enforcement proceeding).² The

² Align contemporaneously filed another separate complaint against ClearCorrect Pakistan (Private), Ltd. and ClearCorrect Operating, LLC, alleging that they violated 19 U.S.C. § 1337. J.A. 7684 n.2. The Commission instituted this investigation (the ’833 Investigation) and has since found a violation of Section 337. *Certain Digital Models, Digital Data, and Treatment Plans for Use in Making Incremental Dental Positioning Adjustment Appliances, the Appliances Made Therefrom, and Methods of Making Same*, Inv. No. 337-TA-833, USITC Pub. No. 531073 (Apr. 3, 2014). We take no position on the merits of the Commission’s opinion in the ’833 Investigation.

Commission then instituted an investigation against six respondents (hereinafter, Intervenors): ClearCorrect Operating, LLC (hereinafter, ClearCorrect USA), ClearCorrect Pakistan (Private), Ltd. (hereinafter, ClearCorrect Pakistan), Mudassar Rathore, Waqas Wahab, Nadeem Arif, and Asim Waheed. 77 Fed. Reg. 25747 (May 1, 2012).

ClearCorrect USA is the successor of ClearCorrect Systems, LLC—a company formed by one of OrthoClear’s customers shortly after OrthoClear ceased its operations and transferred its intellectual property and customers’ patients to Align. The new complaint alleged that ClearCorrect USA works with ClearCorrect Pakistan to provide infringing dental aligners: specifically, that ClearCorrect Pakistan creates in Pakistan the digital data sets used to create the molds on which the aligners are formed, while ClearCorrect USA manufactures and sells aligners in the United States. The complaint also alleged that ClearCorrect Pakistan imports the digital data sets by electronic transmission to ClearCorrect USA. J.A. 7699 ¶¶ 94–95.³

According to Align, Intervenors had violated the Consent Order by importing into the United States, offering for sale, or selling for importation digital data sets used to manufacture dental aligners in the United States, and that those acts (1) used Align’s trade secrets and (2) induced or contributed to the infringement of certain

³ Align maintains that “digital data sets’ are representative of and include all types of relevant data and information, including digital models, digital data and/or treatment paths.” J.A. 7683. According to Align, “[e]ach of the initial, incremental, and final tooth positions, is stored as a digital data set.” *Id.* at 7691.

claims of Align’s patents.⁴ *Id.* at 7698–99 ¶¶ 90–91. Align also alleged that Intervenor should be liable for aiding and abetting the same acts, *id.* at 7700–01 ¶ 102, and that ClearCorrect USA and ClearCorrect Pakistan were each a “successor, assign, or agent” of the original OrthoClear respondents, *id.* at 7686 ¶ 24, 7687 ¶ 31. The named individuals were allegedly “former ‘officers, directors, agents, servants, [or] employees’ of various OrthoClear entities.” *Id.* at 7684.

The Commission instituted the investigation and, in its Notice of Institution (Notice), recommended that the ALJ “may wish to consider” a threshold issue: “whether the accused digital datasets identified in the enforcement complaint . . . are within the scope of the articles covered by the consent order.” *Certain Incremental Dental Positioning Adjustment Appliances and Methods of Producing Same* (“*Dental Appliances*”), Inv. No. 337-TA-562, 77 Fed. Reg. 25747 (May 1, 2012). The Notice also stated that the ALJ’s decision “should be issued in the form of an initial determination (‘ID’) under Commission Rule 210.42(c), 19 C.F.R. § 210.42(c).” *Id.* Following the Commission’s Notice, the ALJ ordered initial briefing of the issue identified by the Commission. J.A. 16173.

In response to the ALJ’s order, Intervenor filed a motion to terminate the enforcement proceeding, arguing that the accused conduct did not fall within the scope of the Consent Order. Align and the Commission’s investi-

⁴ Asserted claim 1 of the ’511 patent is directed to a “computer-implemented method for segmenting an orthodontic treatment path into segments,” and asserted claims 1 and 3 of the ’880 patent are directed to a “method for making a predetermined series of dental incremental position adjustment appliances” using “digital data set[s].”

gative attorney each filed briefs disagreeing with Intervenor's position.

Rather than issuing an "initial determination," the ALJ issued Order No. 57, finding that "[t]he accused digital datasets identified in the enforcement complaint are . . . within the scope of the term 'articles manufactured' as that term appears in the Consent Order." J.A. 27024; *id.* at 66. The ALJ therefore denied Intervenor's motion to terminate and scheduled the trial to begin on January 7, 2013. *Id.* at 28575.

Intervenor sought the Commission's review of Order No. 57, and Align and the Office of Unfair Import Investigations ("OUII") Staff opposed the petition for review. *Id.* at 66. Both Align and OUII Staff argued that the ALJ correctly interpreted the Consent Order. *Id.* at 27280–87, 27538. But, in addition, Align argued that the Commission should also deny review because Order No. 57 was a non-final order, not subject to review by the Commission unless Intervenor moved for interlocutory appeal, which they did not. *Id.* at 27275–79. Specifically, Align identified two reasons why Order No. 57 was non-reviewable: (1) it did not have the elements of an initial determination required by 19 C.F.R. § 210.42(d); and (2) it did not terminate the investigation but merely denied Intervenor's motion for termination, which was an interlocutory decision under 19 C.F.R. § 210.42(c). *See* J.A. at 27275–79.

The Commission ultimately concluded that Order No. 57 constituted an "initial determination," and thus was subject to its review. *Id.* at 87–90. Noting that its initial Notice had indicated that the ALJ's resolution of this threshold issue "should be issued in the form of an initial determination," the Commission treated Order No. 57 as such. *Id.* at 88.

In January 2013, the Commission reversed Order No. 57 and terminated the enforcement proceeding. *Dental Appliances*, 78 Fed. Reg. 2282, 2282–83 (Jan. 10, 2013).

It concluded that the accused digital data sets were not covered by the scope of the Consent Order “because the subject consent order did not contain an express provision prohibiting the electronic transmission of data.” *Id.* at 2283.

The Commission’s opinion confirmed that “it has jurisdiction and authority to reach digital data that are electronically transmitted to a recipient in the United States.” *Id.* at 69. But it reasoned that when it exercised this authority in the past, its remedial orders specifically covered digital data. *Id.* at 70. The opinion identified two instances where the remedial order expressly referred to electronically transmitted data, both involving cease-and-desist orders: *Certain Hardware Logic Emulation Systems and Components Thereof (“Hardware Logic”)*, Inv. No. 337-TA-383, USITC Pub. No. 46647 at 3 (Dec. 3, 1997), and *Certain Systems for Detecting and Removing Viruses or Worms, Components Thereof, and Products Containing Same (“Viruses”)*, Inv. No. 337-TA-510, USTIC Pub. No. 236092 at 3 (Aug. 8, 2005). The Commission remarked that “[t]he inclusion of electronic transmissions in the cease and desist orders was a purposeful choice,” and, because consent orders are enforced like cease-and-desist orders, the “absence of such language in this specific context indicates that electronic transmissions are not covered.” J.A. 72. Consequently, the Commission held that “in cases in which electronic transmissions are at issue, if an order does not specifically reference electronic transmissions, then the order does not cover such importations.” *Id.*

Reviewing the Consent Order at issue in this case, the Commission observed that it “does not contain any such explicit provision” and “never mentions electronic transmission.” *Id.* Accordingly, it held that the Consent Order “does not prohibit such transmissions” and, thus, that Intervenor’s importation of digital data sets into the United States did not violate the Consent Order. *Id.* at

72–73. The Commission declined to reach the question of whether the term “articles manufactured,” as used in the Consent Order, “include[d] digital datasets.” *Id.* at 72. Align appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(6) and 19 U.S.C. § 1337(c).

II. DISCUSSION

A. Commission’s Review of Order No. 57

Our review of the Commission’s determinations is governed by the Administrative Procedure Act. *See* 19 U.S.C. § 1337(c); *see also John Mezzalingua Assocs., Inc. v. Int’l Trade Comm’n*, 660 F.3d 1322, 1334 (Fed. Cir. 2011). We must set aside any findings or conclusions of the Commission that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). The Commission has broad authority to issue rules and regulations governing administration of its cases, but “[i]t is a familiar rule of administrative law that an agency must abide by its own regulations.” *Ford Stewart Sch. v. Fed. Labor Relations Auth.*, 495 U.S. 641, 654 (1990) (citations omitted). Because the Commission circumvented its own rules without waiving, suspending, or amending them, we find that its review of Order No. 57 was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”

At the time of the orders in question, the Commission’s Rules of Practice and Procedure, 19 C.F.R. § 210.1, *et seq.*, explicitly distinguished between rulings by the ALJ that must be issued as “initial determinations” and those that must be issued as “orders.” The rules stated that the ALJ’s rulings on motions “may not be appealed to the Commission prior to the administrative law judge’s issuance of an *initial determination*,” unless the requirements for interlocutory review are satisfied. *See* 19 C.F.R. § 210.24 (emphasis added). Rule 210.42(c) requires that the ALJ “*shall grant* the following types of motions by issuing an *initial determination* or *shall deny* them by

issuing an *order*.” 19 C.F.R. § 210.42(c) (2011) (emphasis added).

One of the types of motions covered by Rule 210.42(c) is a motion for termination.⁵ *See id.* Because Intervenors filed a motion for termination under 19 C.F.R. § 210.21, which the ALJ denied, the ALJ properly denied that motion via an order required by Rule 210.42(c), not as an initial determination.

Whether an ALJ’s ruling issues as an initial determination or an order is important because it determines whether the Commission may review the ALJ’s decision. The ITC’s regulatory regime contemplates that an ALJ’s *grant* of certain kinds of relief, such as to terminate a proceeding or permit a party to intervene, justifies immediate Commission review. But, at the same time, the regulations treat the denial of such requests for relief as not warranting immediate review. Moreover, the regulations provide a mechanism for interlocutory review of Order No. 57 that Intervenors could have used, but did not.⁶ Therefore, the rules clearly prohibited the Commission from reviewing orders like this one.

⁵ Among the other types of motions listed in Rule 210.42(c) are: a motion to amend the complaint or notice of investigation; a motion for a finding of default; a motion for summary determination; a motion for intervention; a motion to suspend an investigation; a motion for forfeiture or return of respondents’ bonds; and a motion to set a target date exceeding 15 months. 19 C.F.R. § 210.42(c) (2011).

⁶ The interlocutory review process permits appeals to the Commission with leave of the ALJ, if the ALJ determines, “in writing, with justification in support thereof, that the ruling involves a controlling question of law or policy as to which there is substantial ground for

The Commission exceeded its authority by reviewing the order below. The ALJ issued an order (not an initial determination) denying (not granting) Intervenors' motion to terminate the investigation. This order was not subject to Commission review under Rule 210.24.

On appeal, the Commission contends that it has discretion to construe the order as an initial determination, but this is not so: the rules expressly state that denials of motions to terminate must be issued as non-reviewable orders. The Commission's regulations explicitly define which ALJ decisions should be considered orders, and decisions denying motions to terminate fall in the latter category.

The Commission is certainly capable of identifying particular types of ALJ decisions that constitute an initial determination for purposes of Commission review. *See, e.g.*, 19 C.F.R. § 210.51(a) (providing that an order setting a target date for completion of the investigation will be considered an order unless the target date exceeds 16 months from when the investigation was instituted, in which case it will be considered an initial determination). By contrast, Rule 210.42(c)—the rule the Commission invoked in its Notice—allows no such distinction.

The 2013 amendments to Rule 210.42(c), which do not apply to the present proceeding, further support this interpretation. New Rule 210.42(c)(1) is similar to the 2011 version with both versions mandating that the

difference of opinion, and that either an immediate appeal from the ruling may materially advance the ultimate completion of the investigation or subsequent review will be an inadequate remedy.” 19 C.F.R. § 210.24(b)(1). The Commission also has discretion to entertain an interlocutory appeal without leave of the ALJ in limited circumstances not applicable here. *Id.* § 210.24(a)(1)–(2).

denial of motions to terminate an investigation shall be accomplished by an order, not an initial determination. 19 C.F.R. § 210.42(c)(1) (effective May 20, 2013); *see also* 78 Fed. Reg. 23474, 23484 (Apr. 19, 2013). Notably, the 2013 amendments designated the denial of certain types of motions—but not motions for termination of an investigation—as an initial determination. *See* 19 C.F.R. § 210.42(c)(2) (effective May 20, 2013) (allowing an ALJ to grant or deny by initial determination motions for forfeiture or return of respondents’ bonds, or motions for forfeiture or return of complainants’ temporary relief bonds). The amendments left unchanged, however, the manner in which the ALJ must resolve motions to terminate an investigation.

Commission precedent also reflects that the Commission has historically declined to treat orders denying motions for summary determinations as initial determinations. *See, e.g., Certain Integrated Circuits, Chipsets, and Prods. Containing Same Including Television (“Integrated Circuits”)*, Inv. No. 337-TA-786, USITC Pub. No. 461450 at 2–3 (Oct. 13, 2011) (reviewing only portion of ALJ’s decision granting motion and refusing to review portion denying motion, observing that “the portion of [the ALJ’s] Order No. 7 denying the motion to terminate is not part of the subject ID,” because Rule 210.42(c) mandates that “the ALJ shall issue a grant of summary determination as an ID”); *Certain Probe Card Assemblies, Components Thereof and Certain Tested Dram and Nand Flash Memory Devices and Prods. Containing Same*, Inv. No. 337-TA-621, USITC Pub. No. 316370 at 2 (Dec. 22, 2008) (admonishing ALJ’s order, purporting to be an initial determination, because order “is not properly designated as an ID since it relates exclusively to the issue of remedy” and that “Rule 210.42(a) provides that the question of remedy shall be addressed in a recommended determination”); *Certain Mobile Telephone Handsets, Wireless Comm’n Devices, and Components Thereof*,

Inv. No. 337-TA-578, 2010 WL 1436458, at *16 (U.S.I.T.C. Dec. 12, 2007) (recognizing that one portion of the ALJ's decision "was not reviewed by the Commission since [it] stemmed from a denial of summary determination and therefore was not an initial determination").

Despite the clear language of its rules and its precedent enforcing those rules, the Commission argues that the Notice superseded its rules by redefining initial determinations for purposes of this proceeding to include a denial of a motion to terminate the proceeding. The Commission may supersede its rules only by waiver, suspension, or amendment of the regulation. 19 C.F.R. § 201.4(b) ("Rules in this chapter may be amended, waived, suspended, or revoked by the Commission only."). Waiver or suspension can be invoked only "when in the judgment of the Commission there is good and sufficient reason therefor." 19 C.F.R. § 201.4(b).

The Commission maintains that identifying and resolving threshold issues is "good and sufficient reason" for waiving Rule 210.42(c). But the Commission did not articulate below any reason, let alone "good and sufficient reason," to waive the regulation. In fact, there is no evidence in the record that the Commission intended to invoke its waiver rule. *Cf. Changzhou Wujin Fine Chem. Factory Co. v. United States*, 701 F.3d 1367, 1377 (Fed. Cir. 2012) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based.") (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). The reasoning offered by the Commission on appeal appears to be improper post hoc rationalization. *See Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962) ("The courts may not accept appellate counsel's post hoc rationalizations for agency action; . . ."); *Action on Smoking & Health v. C.A.B.*, 713 F.2d 795, 799 n.2 (D.C. Cir. 1983) ("When the required explanation of the agency's action is totally absent, or 'palpably inadequate,' it is

difficult to see how a subsequent explanation by the agency on remand could be characterized as anything other than a wholly *post hoc* rationalization.”). The Commission had two chances to invoke waiver or suspension under Rule 201.4(b)—first, in its Notice, second, after Align argued that Order No. 57 was not an initial determination—but did not do so.

When the Commission deemed Order No. 57 to be an initial determination, it did not explain why it had good cause to waive Rule 210.42(c) or cite Rule 201.4(b)’s waiver provisions. The Commission cited only Part 210, (not Part 201), as “the authority for the Commission’s determination.” J.A. 89, 62. Indeed, the Commission itself has rejected the argument that *identical* language in another Notice operated to waive Rule 210.42(c). *Integrated Circuits*, USITS Pub. No. 461450 at 2–3 (observing that “since the portion of [the ALJ’s] Order No. 7 *denying* the motion to terminate *is not part of the subject ID*, the Commission declines to consider” the petition for review, citing Rule 210.42(c), which provides that “the ALJ shall issue a *grant* of summary determination as an ID” and, citing 19 C.F.R. § 210.43(a), “a party may request review of an ID,” but not of an interlocutory non-final order) (emphasis added).

Alternatively, the Commission alleges that the ALJ “mistakenly issued” its decision as an order. Appellee’s Br. 21. We disagree. Nothing in the record suggests that the ALJ made a mistake. This is not a case of merely mislabeling the title as an order because Order No. 57 does not bear any of the hallmarks of an initial determination. Rule 210.42(d) requires that initial determinations include specific information, including “a statement that, pursuant to § 210.42(h), the initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to § 210.43(a) or the Commission, pursuant to § 210.44, orders on its own motion a review of the

initial determination or certain issues therein.” Order No. 57 contains no such statement.

We also do not read Order No. 57 as being inconsistent with the Commission’s Notice. Rather, it appears to us that the ALJ complied with the Notice, which merely stated that the ALJ “may wish to address” this threshold issue and that its decision “should be issued in the form of an initial determination (‘ID’) under Commission rule 210.42(c).” 77 Fed. Reg. at 25747. The ALJ complied with “Commission rule 210.42(c)” by denying the motion to terminate the investigation via an order. So it also complied with the Commission’s Notice.

While we are cognizant that resolving potentially dispositive issues at the outset of the investigation may be advantageous, that goal cannot trump the need for the Commission to follow its own rules and regulations, absent identifying sufficient grounds for waiver or suspension of those rules. Had the ALJ granted Intervenors’ motion to terminate the investigation, that decision would have been issued as an initial determination under Rule 210.42(c), and the Commission could have properly reviewed that initial determination under Rule 210.24, thereby resolving the threshold issue early, as it desired. Or, had Intervenors properly sought interlocutory review, the Commission could have reviewed Order No. 57.

But under these circumstances, the Commission cannot circumvent its own rules. If it desires to do so, Rule 201.4(b) gives it broad authority to waive, suspend, or even amend its rules, none of which happened here. Until it does, its rules are binding and the Commission must follow them. *See United States v. Nixon*, 418 U.S. 683, 696 (1974) (noting that even when an agency could “amend or revoke the regulation defining [its] authority,”

so long as the rule “remains in force the [agency] is bound by it” and a court “is bound to respect and to enforce it”).⁷

B. Interpretation of Consent Order

Because the Commission erred in reviewing Order No. 57, addressing Align’s arguments on the Commission’s interpretation of the Consent Order may be premature. But the Commission may invoke waiver of Rule 210.42(c) properly on remand, propelling this case back to us without the errant procedural flaw but otherwise substantially unchanged. The interests of judicial efficiency, therefore, compel us to note that, should the Commission again rely on its allegedly established practice of requiring remedial orders to explicitly mention digital data for it to be covered, we do not find that reasoning persuasive.⁸

The Commission here concluded that even though it has jurisdiction and authority, as a general matter, over the importation of digital data through electronic transmissions, it has a historic practice of requiring that cease-and-desist orders explicitly reference digital data, and this practice both logically extended to consent orders and

⁷ Because the Commission did not exercise its authority to waive or suspend Rule 210.42(c), we need not consider whether Align was substantially prejudiced. *See Am. Farm Lines v. Black Ball Freight Serv.*, 397 U.S. 532, 539 (1970).

⁸ We assume, for purposes of this opinion, that the Commission has statutory authority to exclude the importation of digital data that enters the United States through electronic transmission. Indeed, the Commission believed that it would have had such authority in this case had the Consent Order expressly referenced it. *Id.* at 69. But we take no position on whether Section 337 permits the Commission to exclude such importations.

put the public on notice as to this requirement. J.A. 69–72.

Based on the authority cited by the Commission, we do not see that any established practice exists, and that whatever practice did exist is not sufficient to place the public on notice. The only two cease-and-desist orders that the Commission can point to included simply a brief parenthetical notation prohibiting electronic transmissions, without any representation that the notation was required or was somehow necessary for consent orders as well. See *Hardware Logic*, USITC Pub. No. 46647 at 3 (Dec. 3, 1997) (prohibiting “transfer (including electronically)”); *Viruses*, USITC Pub. No. 236092 at 3 (Aug. 8, 2005) (prohibiting “import (including electronically)”⁹). While the two orders do refer to electronic transfers or imports, neither indicates that it was critical to do so. Therefore, we do not find that these cases somehow created an established practice sufficient to put the public on notice.

CONCLUSION

For these reasons, we vacate the Commission’s decision and remand for further proceedings, consistent with this opinion.¹⁰

VACATED AND REMANDED

⁹ In fact, the Commission’s own staff did not understand *Hardware Logic* and *Viruses* to articulate such a rule. See J.A. 27725.

¹⁰ We do not address whether “any other articles manufactured” in the Consent Order covers the accused digital data sets. The Commission took no position on this issue, J.A. 72, and we do not sit to review what the Commission has not decided, *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421, 1423 (Fed. Cir. 1984).