

Align Technology
Patent Litigation Case Against ClearCorrect
FAQ as of April 7, 2014

On April 4, 2014, Align Technology received notice that the International Trade Commission (ITC) affirmed the Administrative Law Judge's (ALJ) Initial Determination that the ClearCorrect entities (ClearCorrect Operating, LLC, based in Houston, Texas and ClearCorrect Pakistan (Private) Ltd., based in Lahore, Pakistan) infringe five of the patents asserted by Align in its ITC investigation. The Commission ruled in Align's favor with regard to those patents, issued cease-and-desist orders directed to the ClearCorrect entities, and terminated the investigation.

Below are questions and answers regarding the ITC decision.

Acronyms

International Trade Commission – ITC

Administrative Law Judge – ALJ

Initial Determination – ID

Q: What happened in Align’s ITC litigation against ClearCorrect, and what did the ITC decide on April 3, 2014?

- Align initially filed its complaint in the ITC against ClearCorrect in March 2012, the parties conducted a Section 337 Investigative Hearing (trial) in January 2013, and the presiding ALJ issued his ID in May 2013. In the 816-page ID, the ALJ upheld the validity of each of the 40 claims (spanning 7 Align patents) at issue, found that ClearCorrect US and its Pakistan operation infringed 37 of those 40 claims, and recommended that a cease-and-desist order issue precluding the ClearCorrect entities from continuing to import infringing digital data and using it to make aligners in the United States.
- Pursuant to standard practice, the full Commission decided to review the ALJ’s Initial Determination. As part of that review, the Commission also solicited public briefing on several legal issues related to the case. After several delays, on April 3, 2014, the Commission issued its final decision and opinion resolving the two-year-long investigation.
- The Commission’s final decision did four main things:
 1. It upheld the validity of *all* 40 claims of Align’s 7 asserted patents. This is critical because ClearCorrect has repeatedly stated that it expected the ITC to find Align’s patents invalid, and based much of its defense against Align’s claims on the argument that Align’s patents were invalid, not on the argument that the ClearCorrect process does not infringe. The ITC Staff, the ALJ, and now the Commission itself (each body possessing significant patent expertise) have all rejected ClearCorrect’s invalidity arguments and have found all of Align’s asserted patents valid.
 2. It agreed with the ALJ’s finding that ClearCorrect’s process falls within the scope of all 37 process claims asserted by Align. In other words, both the ALJ and Commission agreed that ClearCorrect’s process is performed according to the steps described in Align’s patent claims. This is significant because it forms the basis for any future infringement analyses, such as in Align’s pending suit against ClearCorrect in the Southern District of Texas, or in any future ITC action.

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3. It found that ClearCorrect violated Section 337 of the import laws as to 18 of the 37 process claims, spanning 5 of the 7 asserted Align patents. Although the ITC found that ClearCorrect practiced *every* element of *all* 37 process claims of *all* 7 patents at issue, it limited its violation findings related to Section 337 for jurisdictional reasons. While the jurisdictional issue is somewhat technical, it can be summarized at a high level as the Commission disagreeing that Section 271(g) of the general patent laws, a statute defining infringement by products made by a patented process, can be used in ITC actions to show infringement (the predicate to a finding of a 337 violation). Although the experienced ALJ found that Section 271(g) could be utilized at the ITC, the Commission ultimately disagreed. Even with this ruling, the Commission still found a violation based on 18 other claims that were infringed by ClearCorrect, more than enough to entitle Align to a cease-and-desist-order (only one claim is required). Importantly, the Commission opinion does not impact Align's ability to rely on these same Section 271(g) arguments in any federal court litigation with ClearCorrect; the Commission only ruled that Section 271(g) was not applicable in the ITC.
4. It issued broad cease-and-desist orders prohibiting the ClearCorrect entities from importing infringing data and using imported data in the process of making aligners.

Q: Is the ITC's decision final?

- Yes, from the ITC's perspective. Pursuant to federal law, the President now has a 60-day period in which he can veto the ITC's decision. If he does not – and that power has been exercised only twice in the past 25 years – the Commission's decision will be considered final on June 2, 2014.
- As with most court or agency decisions, the ITC's determination is appealable. In this case, any appeal will go to the Federal Circuit. ClearCorrect must wait until after the Presidential review period (or until the President makes a decision, if he does so) to file an appeal. At that point, they have 60 days to file.

Q: What happens if ClearCorrect appeals the decision?

- Not much. If ClearCorrect appeals the ITC's decision, it will be handled by the Federal Circuit. In the meantime, it is likely that the cease-and-desist orders would stay in effect. Requests to stay remedial ITC orders are rarely granted. Accordingly, the ClearCorrect entities would continue to be bound by all of the provisions of the cease-and-desist orders throughout the pendency of any appeal, including the reporting and inspection provisions.
- Absent action by Align, the stay of Align's current district court action in Houston will likely remain in effect until the ITC action is final, including the exhaustion of all appeals. Align is considering all possible options to expeditiously proceed against ClearCorrect in

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federal court in order to recover damages and obtain a more wide-ranging injunction against ClearCorrect's activities.

Q: How does the ITC decision affect ClearCorrect's ability to import digital data from Pakistan?

- The Commission found that the ClearCorrect entities violated Section 337 by infringing Align's patents and issued cease-and-desist orders against both ClearCorrect US and ClearCorrect Pakistan. These cease-and-desist orders are effective immediately (although ClearCorrect can continue accepting new cases until April 10, 2014).
- Under the terms of these orders, ClearCorrect can only import the infringing digital data from ClearCorrect Pakistan to treat existing patients (*i.e.*, patients whose cases were submitted to ClearCorrect before April 10, 2014).
- Both ClearCorrect entities are prohibited by law from importing infringing digital data for new patients as well as advertising or selling the infringing system to new patients.

Q: Can ClearCorrect avoid infringement by simply changing where it creates the digital data?

No, for several reasons:

- *First*, the Commission upheld the validity of *all* of the claims of Align's 7 asserted patents, and found that ClearCorrect practiced *every* element of 37 claims. Simply moving the location of **where** ClearCorrect infringes Align's patents (*e.g.*, moving out of Pakistan) is no more than an ill-conceived delaying tactic. No matter where ClearCorrect moves, its current process is still infringing. Because that process has been found to infringe (even as ClearCorrect attempted to avoid infringement by breaking up its process between two separate entities in two separate countries – a process the ALJ called a "sham"), combining the infringing process back to one country or one entity will not change the ultimate infringement analysis. Any attempt to skirt the ITC's jurisdiction by domesticating the process would actually make the federal court infringement case against ClearCorrect much stronger (see "*Third*," below)
- *Second*, the Commission has found that even setting aside ClearCorrect Pakistan's involvement, ClearCorrect US directly infringes 2 of Align's patents based solely on the processes it currently performs in Houston. Thus, altering ClearCorrect Pakistan's location or method does not change the finding that ClearCorrect's current processes in the United States alone infringe Align's valid patents.
- *Third*, Align has another, separate case against ClearCorrect pending in federal court, and that case is not limited by the unique jurisdictional and statutory requirements present in the ITC. Thus, while the Commission declined to find a violation on some of Align's claims based on ITC-specific jurisdiction issues, those issues are irrelevant in federal court. Moreover, while the Commission's decision is not technically binding on any future federal court proceeding, its infringement and validity findings are considered

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very persuasive because they are made by patent experts in a specialized forum dominated by patent litigation.

Q: What about ClearCorrect doctors or their patients? If an orthodontists or GP dentist submits a case to ClearCorrect after April 10, 2014, can ClearCorrect use its existing process to make aligners for that patient? What about the assurances ClearCorrect is providing?

- No, after April 10 ClearCorrect cannot use its existing process to make aligners and doing so could subject them/it to fines and/or criminal penalties. Moreover, as part of the cease-and-desist orders, the ITC has required ClearCorrect to submit data about its process and its customers so that it and Align may audit ClearCorrect's compliance with the ITC's decision.
- Additionally, while the ITC may permit ClearCorrect to continue to serve existing patients whose cases were ordered before April 10, 2014, the federal court may not. Align intends to seek damages in that litigation for all past and continued infringement of Align's patented processes.
- Doctors and patients who commence treatment with the ClearCorrect product after April 10, 2014 face the possibility of their treatment being interrupted or suspended mid-treatment.
- Given that many of the assurances provided by ClearCorrect thus far have turned out to be wrong ("the Align patents are invalid," "ClearCorrect does not infringe," "ClearCorrect will prevail at the hearing," "the ALJ is wrong and the Commission will find the patents invalid and not infringed," etc. etc.), doctors and patients should carefully consider ClearCorrect's most recent assurances (about a new "streamlined" process, or claims that the Federal Circuit will reverse everything etc. etc.) in light of ClearCorrect's prior track record for self-serving and ultimately inaccurate assurances.

Q: Does ClearCorrect have to pay Align any money?

- Not yet, because monetary damages were not available at the ITC. But the ITC found that ClearCorrect has been infringing Align's patents for years, and if the federal court agrees, ClearCorrect could be liable for millions of dollars in past damages. This is true even if ClearCorrect now attempts to change its processes. And because ClearCorrect was aware of Align's patent claims since before it commenced operation, Align will seek treble damages to remedy ClearCorrect's willful infringement.
- Moreover, ClearCorrect could also be fined (up to \$100,000 per day) if it violates the cease-and-desist order and may even incur criminal sanctions if it fails to accurately report its activities under the ongoing reporting obligations imposed by the cease-and-desist orders.