USIJ White Paper on *Fintiv* Doctrine

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The Patent and Trial Board ("PTAB") has come under political pressure for its use of the "*Fintiv*" doctrine. The *Fintiv* doctrine, named for the case *Apple v. Fintiv*, IPR2020-00019, recognizes that the PTAB has discretion on whether to institute proceedings to challenge the validity of a patent, and that the PTAB may exercise that discretion to deny instituting such proceedings when its work would be duplicative of work already being done by another judicial body, such as a district court or the International Trade Commission (ITC). The *Fintiv* doctrine arises from the collision course inherent when two different governmental bodies are tasked with rendering decisions on the same issue at more or less the same time. The PTAB, which has now been in operation for about eight years, has developed its own jurisdictional guidelines on when it will decline to take action that will disrupt the work of another tribunal. This prudence is to be commended.

The political pressure upon the PTAB has come under the guise of reducing drug prices. The theory is that the PTAB has invoked the *Fintiv* doctrine to decline to institute its proceedings in cases involving pharmaceutical patents, and that, if the PTAB had instead instituted those proceedings, and if the PTAB had invalidated those patents, then the striking of those patents would have paved the way for generic versions of those drugs, thereby reducing drug prices. This theory is stretched beyond any semblance of support. Neither the PTAB, nor its *Fintiv* doctrine, is the cause of high drug prices.

The PTAB has issued 604 rulings that refer to the *Fintiv* doctrine, as of October 29, 2021.[1] There are only four cases in which the PTAB relied on the *Fintiv* doctrine to decline to institute its proceedings in a case involving a pharmaceutical patent. And two of those four cases involve the same patent family. Thus, there are only three distinct disputes over pharmaceutical patents over which the PTAB declined to institute its proceedings due to the *Fintiv* doctrine. Those three disputes are:

- IPR2020-00440, *Mylan Laboratories Ltd. V. Janssen Pharmaceutica NV*
- IPR2020-01317, *Regeneron Pharmaceutical, Inc. v. Novartis Pharmaceuticals Corp*.
- PGR2021-00030 & PGR2021-0042, *Daiichi Sankyo, Inc. v. Seagen Inc. f/k/a Seattle Genetics, Inc*.

[1] Steven C. Carlson, Robins Kaplan LLP, *Fintiv Denials in Drug Cases*, https://www.robinskaplan.com/resources/publications/2021/11/fintiv-denials-in-drug-cases

Accordingly, less than half a percent of the PTAB's rulings that recite *Fintiv* are decisions to deny instituting proceedings in pharmaceutical cases. In other words, 99.5% of the institution rulings in which the PTAB refers to *Fintiv* are not disputes over pharmaceutical patents.

Big Tech companies dislike the *Fintiv* doctrine. Those Big Tech companies are leading the charge to force the Patent Office to abandon the *Fintiv* doctrine, because those companies rely on the PTAB as a means of delaying and avoiding trial on their patent infringements.

Complaints over drug prices are a smoke screen to obscure the real motivation behind pressuring the PTAB to abandon the *Fintiv* doctrine. The 0.5% of cases that involve *Fintiv* denials on pharmaceutical patents are not the cause for consternation. It is the other 99.5% of cases, and particularly those cases in which Big Tech is seeking an escape from its infringement trials, that is the cause of the lobbying uproar over *Fintiv*. Drug prices are simply a false pretense for attempting to divest the PTAB of its discretion to govern its own jurisdiction and to avoid interfering in the proceedings of other courts.