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Smith+Nephew

December 2, 2020

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

Patent Board
c/o Scott C. Weidenfeller
Vice Chief Administrative Patent Judge
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313-1450

Via Federal eRulemaking Portal at <https://www.regulations.gov>
Docket No. PTO-C-2020-0055

RE: Comments of Smith & Nephew, Inc. on Discretion to Institute Trials before the Patent Trial and Appeal Board appearing at 85 Federal Register 66502-66506 (October 20, 2020)

Dear Under Secretary Iancu and Judge Weidenfeller:

Smith & Nephew appreciates the opportunity to comment on proposed rulemaking related to discretionary denials of petitions. Smith & Nephew is a global medical device company focused on helping restore the active lives of patients by developing innovative wound care, orthopedic, and sports medicine products. Smith & Nephew holds over 5000 patents and employs over 16,000 people worldwide (1500+ patents in the United States).

Smith & Nephew writes from the perspective of a medical device company often engaged in patent litigation with competitors. When faced with lawsuits alleging infringement, Smith & Nephew frequently turns to the PTAB when the asserted patent claims are believed to be invalid. The IPR process has consistently allowed Smith & Nephew to resolve patent disputes efficiently and economically, before a panel of experts, as Congress intended when it enacted the AIA. H.R. Rep. No. 112-98, pt. 1, at 40 (2011), 2011 U.S.C.C.A.N. 67, 69 (Congress designed the AIA “to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs.”).

Smith & Nephew believes that the IPR process should remain a viable means for challenging patents of questionable validity. When a patent owner obtains and asserts patents claiming information that is neither new nor non-obvious, IPRs provide an economically efficient means to challenge the validity of such patents before sophisticated APJs applying an appropriate burden of proof. For these reasons, IPRs should continue to be reliably available to adjudicate invalidity issues as Congress intended.

Two proposals threaten to significantly reduce the viability of IPRs: (1) the proposal to adopt a bright-line rule precluding patent claims from being subject to more than one AIA proceeding, regardless of the circumstances; and (2) discretionary denials in view of co-pending litigation. Smith & Nephew writes to address these two proposals.

I. The “One-and-Done” Proposal Should Be Rejected

Respectfully, the PTO should reject any bright-line rule that precludes patents from being subject to more than one AIA proceeding. There are two separate problems with such an approach—one concerning the issue of “serial petitions” and the other concerning “parallel petitions.” As to serial petitions, such a rule would be fundamentally unfair, counter to efficiency goals, and would have the effect of forcing a company like Smith & Nephew to divert resources to address patents that may never be asserted against the company. As to parallel petitions, such a rule would neglect the reality that multiple petitions are often necessary given significant differences in structure and scope of claims within a single patent; a “one-and-done” approach would have the effect of degrading petition quality and ultimately creating additional work for the PTAB and uncertainty on appeal.

A. Serial Petitions Can Be Necessary in View of Patentees’ Litigation Strategies

If a patent owner chooses to sue multiple companies, then each defendant should have an opportunity to advance a novel argument in an IPR proceeding, and should not otherwise be saddled by the first filer’s decisions with respect to counsel, budget, prior art selection, argument selection and emphasis, claim construction, or other strategic decisions.

In establishing any rules for discretionary denials, Smith & Nephew further believes that the PTO should take into account choices of the patent owner. Smith & Nephew has faced assertions by patent owners who have chosen to: (1) sue competitors in serial suits, including first filing suit against competitors having lesser economic risk (and thus more likely to settle without a full adjudication of invalidity issues), (2) secure expansive sets of patent claims and dozens of patents from a single priority filing, and (3) assert several patents with hundreds of claims against a single product.

Some have suggested that the rules should prohibit more than one IPR petition from being filed against a patent, without regard to the choices made by the patent owner, including the choice to sue multiple companies over many years. Under such a construct, in order to have an administrative remedy, a company must be the first to file an IPR petition or be forever precluded from filing an IPR petition. Such a rule would force companies to monitor all patent litigation against competitors and rush to file IPR petitions as soon as a patent owner sues a competitor for

patent infringement. A one-and-done rule would also require companies to monitor PTAB filings by competitors to determine whether joinder is appropriate to influence an already-filed petition. In reality, budget constraints limit a company's ability to file IPR petitions on patents that have not been, and may never be, asserted; particularly when portfolios are vast and a company focuses on many sectors.

Respectfully, Smith & Nephew believes that any rule should continue to apply a presumption in favor of institution when a petitioner demonstrates a reasonable likelihood of successfully challenging the patentability of at least one claim of a patent, and deviations from the presumption should be based upon the totality of the circumstances, including the patentee's litigation and prosecution strategies.

B. Parallel Petitions Can Be Necessary In View of Patentees' Claiming Strategies

Similarly, no company should be required to shoehorn challenges against a particular patent into a single petition in situations where the claim set and/or applicable prior art are such that multiple petitions would be more appropriate. The PTO's requirements for petitions are considerably more stringent than the "notice pleading" requirements in district court. Similarly, the PTO consistently refuses to permit petitioners to supplement and correct deficient petitions later on in the process. These procedures are logical and consistent with the AIA's purpose to create a more efficient, streamlined, and predictable alternative to litigation. However, if coupled with a rigid "one-and-done rule," they would provide patent owners with an unwarranted and inequitable tactical advantage while incentivizing them to assert and maintain as many claims as possible within a single patent—then pick apart the single petition on the ground that it is insufficiently detailed and particularized. The PTAB would likewise find itself having to scrutinize potentially abbreviated arguments from challengers that in the ordinary course would have filed multiple petitions which would have been clearer, more detailed, and ultimately easier for the PTAB to assess. These concerns are heightened given the Federal Circuit's rejection of "the PTO's position that the Board is free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016).

Here again, Smith & Nephew's experience highlights the dangers of a "one-and-done" approach. Smith & Nephew has faced patent owners that have obtained patents with over 100 claims, necessitating parallel petitions to address all the claims. Smith & Nephew has also been accused on patents that had a smaller number of claims, but which had been drafted such that there were subtle yet important distinctions ultimately requiring multiple petitions. In one instance, for example, Smith & Nephew once faced a patent with eleven claims—three independent and eight dependent. Given distinctions among those claims and the relevant prior art, Smith & Nephew determined that it was necessary to file two petitions in order to present its unpatentability case at the level of detail the PTAB requires. The petitions were both successful. But it is uncertain whether the result would have been the same (despite the strong prior art) under a "one-and-done" rule or even under the subsequently implemented guidance in the current Consolidated Trial Practice Guide. Given this experience, Smith & Nephew believes that any discretionary denial analysis concerning parallel petitions should take a holistic, case-specific approach rather than (1) focusing on the sheer number of claims, (2) emphasizing other bright-line rules (e.g., whether or

not there is a priority question), or (3) beginning with the presumption that parallel petitions “should be rare.”

Further, a “one-and-done” rule would become even more problematic over time as patent applicants took advantage and prosecuted cases with an eye toward obtaining claim sets difficult or impossible to challenge effectively in a single petition. Even today, Smith & Nephew is aware of recommendations of prosecution strategies that account for the Consolidated Trial Practice Guide’s suggestion that parallel petitions “should be rare.”

For the foregoing reasons, Smith & Nephew encourages the PTO reject a one-and-done rule both with respect to serial petitions and parallel petitions.

II. Petitions Should Be Evaluated on the Merits, Not Denied Due to Co-Pending Litigation

The PTO should overturn *NHK/Fintiv* and avoid creating a rule that requires or allows administrative patent judges to deny petitions based on co-pending litigation. Such a rule is contrary to the AIA, which addresses co-pending litigation and sets a one-year deadline for filing petitions after the patent owner serves an infringement complaint. 35 U.S.C. § 315(b). Congress fully intended the two proceedings to occur in parallel. If a petition shows a reasonable likelihood that the challenged claims are invalid (under the PTO’s preponderance of the evidence standard), the IPR should be instituted and the patent should be reviewed by trained PTAB judges. The purpose of IPRs was to improve patent quality and ensure integrity in the patent system. That is accomplished by having trained judges review the patent when a petitioner makes the required showing. It is contrary to the AIA to deny a meritorious petition because a jury (not consisting of APJs) may be deciding validity under a higher evidentiary standard (clear and convincing).

Denying an IPR petition based upon the current trial date, or the stage of co-pending litigation, is unwise. Patent owners often sue on numerous patents with large numbers of claims. Companies may not appreciate which claims should be challenged until after a patent owner is required to identify the asserted claims, and then narrow them to a reasonable number for *Markman* and later trial. It thereafter takes time to develop an IPR strategy and prepare quality petitions. Indeed, in drafting the AIA, Congress extended the § 315(b) deadline to one year from the originally proposed six months to “afford defendants a reasonable opportunity to identify and understand the patent claims that are relevant to litigation.” *See* 157 Cong. Rec. S5429 (daily ed. Sept. 8, 2011). Thus, the one year allotted by Congress for filing IPR petitions after service of a complaint should be the rule. Congress set the one year deadline (after originally considering just six months) to balance competing policy considerations and ultimately result in well-focused petitions challenging claims significant to the litigation. *NHK/Fintiv* upsets this balance and ultimately increases the Board’s workload by pressuring challengers to file on all potentially relevant claims even when many quickly drop out of the associated litigation.

Denying an IPR petition based upon the current trial date also neglects the reality that such trial dates are frequently extended. *NHK* and *Fintiv* each serve as cases in point. In *NHK*, the PTAB denied instituted on September 12, 2018 and cited the district court’s scheduled trial date of March 25, 2019. Two days later, on September 14, 2018, the district court delayed the trial by a month—

the first of *four* extensions that ultimately resulted in the trial being scheduled for November 2019—well after the September 2019 date when the PTAB would have issued a final written decision but for the discretionary denial. Similarly, in *Fintiv*, after the PTAB denied institution, the district court rescheduled the trial for a date that was past the deadline by which the final written decision would have issued had the PTAB instituted IPR.

Smith & Nephew appreciates the PTO’s commitment to improving administrative review proceedings created by Congress in the America Invents Act and hopes that the PTO will consider its comments before implementing bright rules with respect to discretionary denials. In particular, Smith & Nephew hopes that the PTO will avoid a “one-and-done” rule for IPRs when a patent owner has chosen to sue multiple companies, particularly in serial order over a long period. Smith & Nephew also strongly favors instituting IPR petitions based on the merits if filed within one year of the patent owner serving an infringement complaint.

Sincerely,



Mark J. Gorman
Associate General Counsel - Intellectual Property, Regulatory and R&D
Smith & Nephew, Inc.