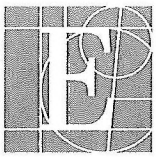

Edwards

December 3, 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 Edwards Lifesciences Corporation on Discretion to Institute Trials before the Patent Trial and Appeal Board appearing at 85 Federal Register 66502-66506 (October 20, 2020)

Dear Director Iancu and Judge Weidenfeller:

Edwards Lifesciences appreciates the opportunity to comment on proposed rulemaking related to discretionary denials of petitions. Edwards is a global-leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, Edwards works with clinicians to develop innovative technologies, including never-been-done-before transcatheter heart valve replacement and repair devices developed to help patients avoid open-heart surgical procedures, or receive treatment in circumstances where previously they could not, and live longer, healthier, and more productive lives. Edwards strives for big, bold advancements that will fundamentally change the practice of medicine.

Edwards, having previously asserted its patents against competitor Medtronic and collected over $1 billion due to Medtronic's infringement, believes in a strong patent system that is fair and equitable to inventors. In 2019, Edwards spent $753 million on research and development (up 21% from the previous year), which was 17% of its sales. Globally, Edwards employs approximately 15,000 people, including more than 2,000 engineers. Headquartered in Southern California, the majority of Edwards' sales occur in the United States. Edwards' R&D investments and its patient-focused innovations are protected by almost 1,100 patents, with almost 800 U.S. patent applications pending.

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Edwards has faced patent infringement lawsuits from competitors on questionable patents, including from a major medical device company who had yet to launch a competing product in the United States and who lacked FDA approval to do so. Notwithstanding Edwards' life-saving heart devices each being one of the few options for patients, Edwards has been confronted with questionable patents when the patent owners either could not compete in the marketplace or were falling behind in innovation. Filing IPRs against those questionable patents helped Edwards "limit unnecessary and counterproductive litigation costs," while improving "patent quality" through a "more efficient and streamlined patent system." See House Report at 40. In one of those litigations, a Federal District Court jury found a patent not invalid even though the Patent Office had already determined the claims were unpatentable in an IPR proceeding, which was later affirmed by the Federal Circuit Court of Appeals. Accordingly, Edwards believes that the IPR process should remain a viable venue for challenging invalid patents.

I. Serial Petitions Should Only be Limited by 35 U.S.C. § 325(d)

On balance, Edwards believes that the Patent Office's denial of meritorious challenges to claims on procedural grounds may unnecessarily increase costs for the parties and undermine the purposes of the AIA to provide an expert administrative review of patents with a lower burden of proof on validity. *See* 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.").

But, pursuant to 35 U.S.C. § 325(d), Edwards supports a rule that addresses petitions challenging patents that are involved in another proceeding before the Patent Office, particularly when the same prior art or arguments previously were presented to the Patent Office in an IPR. If the Patent Office were to implement a bright-line rule, it should strictly follow 35 U.S.C. § 325(d) and only decline to institute when the same or substantially the same prior art or arguments were presented in another petition by the same petitioner. Grounds that involve different references than previously presented grounds should be presumed not to be "substantially the same."

To the extent the Office intends to adopt a rule with a case-specific analysis, it should take into account the conduct of both petitioner ***and patent owner.*** In contrast, the *General Plastic* factors overlook the actions of the patent owner, which often create the need for serial petitions. Ignoring the patent owner's actions allows the patent owner to make procedural choices in related proceedings involving the challenged patent to avoid the best substantive review by the Patent Office.

For example, patent owners may serially assert their patents against multiple defendants over the course of multiple years. Later-sued petitioners may not be able to overcome a Section 325(d) challenge under the *General Plastic* factors that consider previous petitions and whether patent owner has filed its preliminary response or an institution decision issued. Congress did not intend inter partes review to be available only to the first-sued petitioner, or the petitioner who filed the first petition when the patent owner sues different,

unrelated defendants over a period of time. Congress also did not intend to place a large burden on all market participants to monitor IPR filings and lawsuits so they could win a race to file for IPR at the Patent Office to manage risk on a hypothetical future lawsuit that may or may not ever happen. A rule prohibiting the later, second-sued petitioner from having a chance at an IPR is fundamentally unfair, allowing patent owners to pick and choose where and when to file lawsuits against which defendants, all of which, except the first, will be denied administrative relief in favor of the litigious patent owner with no improvement in patent quality.

Edwards suggest the following additional factors that focus on the actions of the patent owner and the grounds in the petitions: whether the patent owner's conduct impacted the timing of a later petition filed against the patent; whether the later-filed petition presents different grounds (prior art combinations or arguments) than the earlier petition; and the merits of the petition.

Valve I and Valve II should be rejected. The relationship between different challengers should not be a factor. The *General Plastic* factors sufficiently address serial petitions by challengers trying to game the system by waiting to file the second petition until after the POPR or institution decision in order to fill gaps in the first petition. The current analysis under *Valve I* and *Valve II* of the relationship between the petitioners causes problems between customers and suppliers who each may want to file their own petitions or similar problems between different defendants in a joint defense group who each need to rush to be first to file a petition.

Finally, the Patent Office should reject any bright line rule that precludes claims from being subject to more than one AIA proceeding regardless of the circumstances as fundamentally unfair and counter to efficiency goals. A so-called one-and-done rule could potentially create a race to the Patent Office by forcing companies to monitor competitor litigation and IPR filings to determine whether to be the first to file an IPR, even though it had not yet (and may never be) sued for infringement of that patent. The public should be able to invest their resources in challenging only the most relevant patents, as selected by the patent owner, and should not have to race their competitors or others to the Patent Office.

II. Parallel Petitions Should Be Evaluated on Their Merits

On balance, Edwards believes that the Board's denial of meritorious challenges to claims on procedural grounds may unnecessarily increase costs for the parties and undermine the purposes of the AIA to provide an expert administrative review of patents.

To the extent the Patent Office intends to adopt a rule with a case-specific analysis regarding parallel petitions, the Board should consider the ***patent owner's*** actions as part of the analysis. The patent owner's prosecution and assertion choices, along with other circumstances such as priority disputes, often necessitate multiple petitions due to space limitations. Yet the current guidance in the Consolidated Trial Practice Guide does not consider the patent owner's actions.

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Edwards believes that the Patent Office should take into account the choices of the patent owner when drafting any rules restricting parallel petitions, including:

(a) the number of claims patent owner included in the challenged patent

(b) whether the patent owner has asserted a large number of claims in litigation or failed to specify the asserted claims;

(c) whether the patent owner has disclosed its claim constructions, infringement positions, and validity positions in the litigation at the time parallel petitions were filed;

(d) if different challenges are pursued in parallel petitions based on different claim construction positions, the reasonableness of the alternative claim constructions advanced by the petitioner;

(e) whether there is a dispute about a priority date requiring arguments under multiple prior art references;

(f) whether petitioner addresses secondary considerations of obviousness in its petition; and

(g) the merits of the petition.

III. The Patent Office Should Disregard Co-Pending Litigation When Deciding Institution

Edwards believes that the Patent Office lacks authority to deny a petition based on co-pending litigation. The Patent Office 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). This bright-line rule confirms that Congress intended the two proceedings to overlap, and even contemplated that the litigation could advance for one year before filing an IPR petition, and still meet the overall need of the public to have increased patent quality and efficiencies.

Congress enacted IPR to provide district court defendants with an administrative alternative to litigation. House Report at 48. Many now cite the "alternative" language to argue that there should be no overlap between district court litigation and IPR. But that was never the intent. Congress knew how to and chose to bar institution where a petitioner had previously challenged the patent's validity in a declaratory action, 35 U.S.C. § 315(a)(1), but did not bar institution due to co-pending litigation. Congress also allowed the Patent Office to determine how an IPR will proceed, including stay or termination, when multiple proceedings involving the patent are pending before the Patent Office, *id.* § 315(d), but did not make such an allowance for co-pending district court actions.

One reason Congress provided a twelve-month window for filing IPRs was to allow parties to avail themselves of "the expertise of the Patent Office on questions of patentability."

157 Cong. Rec. S1352 (2011) (Sen. Udall). Indeed, IPR was "designed in large measure to simplify proceedings before the courts and to give the courts the benefit of the expert agency's full and focused consideration of the effect of prior art on patents being asserted in litigation." *NFC Tech. LLC v. HTC Am., Inc.*, 2015 WL 1069111, at *4 (E.D. Tex. Mar. 11, 2015) (Bryson, J., sitting by designation). Edwards has seen these policies play out. Before *NHK/Fintiv*, Edwards successfully sought a stay of litigation pending IPR, following the Patent Office's reasoned institution decision. In another matter, the district court denied a stay and the IPR and litigation proceeded in parallel with the Patent Office finding the claims unpatentable prior to the district court trial. Despite the Patent Office holding the claims unpatentable, the district court allowed the patent owner to proceed to a jury trial on its infringement claims. During trial, Edwards had less than two hours to present all of the evidence on invalidity. Based upon the trial presentation, the jury found the same claims previously held unpatentable by the Patent Office to be not invalid. The Federal Circuit affirmed the Patent Office's unpatentability decision on appeal. Had the Patent Office issued a discretionary denial, it would have deprived the public of an accurate determination of patentability and the petitioner of full and fair consideration of patent validity issues. Further, the patent owner's choice to proceed with trial and not stipulate to a stay wasted court and party resources and is an example of what could happen if the Patent Office continues with discretionary denials based on co-pending litigation.

More recently, Edwards has had IPRs denied because of co-pending litigation with an early trial date, only to see those trial dates inevitably shift. In one litigation, Edwards timely filed two IPR petitions approximately six months after the patent owner served its infringement complaint. The Patent Office, however, denied the petitions under *NHK* in part because the district court's scheduling order set the trial date to occur before a final written decision would issue and the Patent Office speculated that the court intended to preserve the trial date. Two weeks later, the district court vacated the trial date and eventually reset it for three months later, before vacating it once again. Thus, the panel erred in its speculation that the trial would occur before a final written decision. Such errors also incurred in *NHK*, *Fintiv*, and numerous other cases.

Congress contemplated that IPRs would frequently result in a stay of the district court litigation, but left it to the sound discretion of the district court judge to make that determination. It never intended that administrative patent judges would make the decision to proceed based on their best guess as to the timing of a district court proceeding. Moreover, a patent owner always has the option to stipulate to a stay of the litigation and allow the IPR to be a true alternative to litigation. Under the current *NHK/Fintiv* rule, patent owners have no motivation to do so; rather, they are motivated to push for an aggressive district court schedule that may eliminate the defendant's ability to successfully petition for IPR of the patent. To have the Patent Office take the side of patent owners on speculative procedural grounds outside the control of the Patent Office does little to protect the public from poor quality patents.

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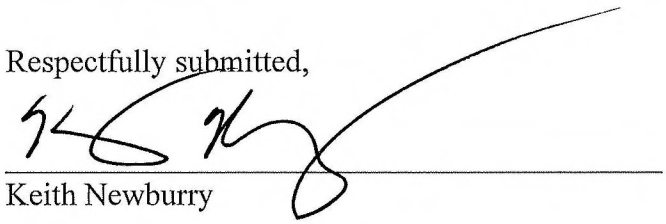
In conclusion, if a petition that is filed within the twelve-moth window allotted by Congress shows a reasonable likelihood that the claims are unpatentable, the IPR should be instituted and the patent should be reviewed by administrative patent judges.

IV. Other Considerations

The Patent Office frequently relies upon 35 USC § 325(d) to exercise its discretion to deny petitions that allegedly rely upon prior art and arguments previously before the Patent Office during prosecution. Edwards has been subject to several such discretionary denials. In each case, neither the prior art nor the arguments were presented to the Patent Office during prosecution. Rather, in some cases, the patent owner merely listed the reference on an Information Disclosure Statement with hundreds of other references. Based on a mere checkmark or a failure to cross off a reference, the Patent Office treated the Examiner as having "considered" the reference even though the Examiner never applied the reference. Given the sheer number of references that can be presented by a patent owner in an IDS, denying IPR because a reference was listed in an IDS defies the practicalities of ex parte patent prosecution.

Respectfully submitted,



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