Trials@uspto.gov 571.272.7822

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION, Petitioner,

v.

BOSTON SCIENTIFIC SCIMED, INC., Patent Owner.

Case IPR2017-01301 Patent 6,915,560 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and STACY B. MARGOLIES, *Administrative Patent Judges*.

TARTAL, Administrative Patent Judge.

DECISION Denying Institution of *Inter Partes* Review 37 C.F.R. § 42.108

I. INTRODUCTION

On April 19, 2017, Edwards Lifesciences Corporation ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting institution of *inter partes* review of claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 (the "Challenged Claims") of U.S. Patent No. 6,915,560 B2 (Ex. 1201, "the '560 patent"). Boston Scientific Scimed, Inc. ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *See also* 37 C.F.R. § 42.4(a).

The Petition is the *third* petition filed by Petitioner challenging the same claims of the '560 patent. Petitioner filed its first petition against the Challenged Claims of the '560 patent on October 14, 2016, in IPR2017-00072 ("IPR-072"). *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc.*, Case IPR2017-00072, Paper 1 (the "IPR-072 Petition"), 44–93. Petitioner filed its second petition on December 7, 2016, against the Challenged Claims of the '560 patent in IPR2017-00444 ("IPR-444"). *Edwards Lifesciences Corp. v. Boston Scientific Scimed, Inc.*, Case IPR2017-00444, Paper 1 (the "IPR-444 Petition"), 49–97.

On April 21, 2017, we declined institution of *inter partes* review of the Challenged Claims of the '560 patent in IPR-072. IPR-072, Paper 8 (the "IPR-072 Institution Decision"), 11. On June 29, 2017, we instituted *inter partes* review of the Challenged Claims of the '560 patent in IPR-444.

IPR-444, Paper 9 (the "IPR-444 Institution Decision"), 25. Oral argument in IPR-444, if requested by the parties, is scheduled for March 15, 2018. IPR-444, Paper 8, 8.

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a). For the reasons explained below, we exercise our discretion to not institute *inter partes* review on any of the Challenged Claims of the '560 patent in this case.

II. BACKGROUND

A. The '560 Patent

The '560 patent, titled "Apparatus for Contracting, Loading or Crimping Self-Expanding and Balloon Expandable Stent Devices," issued July 12, 2005, from U.S. Application No. 10/444,807 (the '807 application), filed May 23, 2003. Ex. 1201. The '807 application was a division of U.S. Application No. 09/966,686, filed on October 1, 2001 (issued as U.S. Patent No. 6,823,576), which was a continuation of U.S. Application No. 09/401,218 (the '218 application), filed on September 22, 1999 (issued as U.S. Patent No. 6,360,577). *Id.* The '560 patent generally relates to a device "capable of crimping a stent uniformly while minimizing the distortion of and scoring and marking of the stent due to crimping." *Id.* at 2:26–29. IPR2017-01301 Patent 6,915,560 B2



Figure 4A of the '560 patent is reproduced below.



Figure 4A illustrates "a partial front view of an embodiment of the inventive apparatus." Ex. 1201, 4:1–2. Actuation device 138 includes rotatable actuation plate 142 and eight coupled blades 106 disposed about reference circle 114 to form aperture 118. *See id.* at 4:46–49. "Each blade 106 is engaged to actuation plate 142 via a cam follower bearing 150 disposed in radial slot 146 and attached to mounting means in slotted end 134." *Id.* at 5:19–21. "Each bearing 150 extends from a linear slide 154." *Id.* at 5:22.

"In use, as actuation plate 142 is rotated in a clockwise direction, the clockwise motion of the actuation plate is translated into linear motion of each linear slide 154 and blade 106 via bearing 150." *Id.* at 5:46–49. "Each blade 106 moves outward in a direction parallel to the radius 126 . . . resulting in the opening of aperture 118." *Id.* at 5:49–52.

B. Illustrative Claim

Challenged claims 1, 10, 18, 27, 37, 39, and 40 are independent.

Claim 1 is illustrative of the claimed subject matter and is reproduced below:

- 1. A stent crimper comprising:
- a plurality of movable dies arranged to form an iris having a longitudinal axis, the iris defining an aperture, the dies disposed about the aperture and between stationary end-walls which are disposed about the longitudinal axis, at least one of the stationary end-walls operatively engaged to the dies at distinct connection locations such that the number of distinct connection locations and the number of dies are the same;
- each die having a first straight side and a second straight side, the first straight side and the second straight side conver[g]ing to form a tip; wherein a portion of the first straight side of each die faces the aperture, each first straight side parallel to the second side of an adjacent die.

Ex. 1201, 10:8–22.

C. Related Proceedings

In addition to the *inter partes* review of the Challenged Claims of the '560 patent instituted in IPR-444 and the petition denied in IPR-072, discussed above, the parties indicate that the '560 patent is asserted in the United States District Court for the Central District of California, in a case captioned *Boston Scientific Corp. et al. v. Edwards Lifesciences Corp.*, Case No. 8:16-cv-0730 (C.D. Cal.). Pet. 11; Paper 3, 2.

D. Real Parties in Interest

Petitioner identifies only itself as a real party in interest. Pet. 11. Patent Owner identifies itself and Boston Scientific Corp. as real parties in interest. Paper 3, 2.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent on the following grounds:

References	Basis	Claims challenged
Yasumi ¹ and Williams ²	§ 103	1, 2, 6, 8–10, 14, 15, 18, 23,
		1, 2, 6, 8–10, 14, 15, 18, 23, 25, 27, 28, 31, 33, 37, and 40
Yasumi, Williams, and Morales 2 ³	§ 103	11, 17, 19, 26, 34, 35, and 39

Petitioner relies on the Declaration by Neil Sheehan, dated April 19, 2017, (Ex. 1205) as support for its challenge.

III. ANALYSIS

A. Discretionary Non-Institution Under 35 U.S.C. § 314(a)

The Board has discretion not to institute an *inter partes* review.

35 U.S.C. § 314(a); 37 C.F.R. § 42.108(a); *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) ("First of all, the PTO is permitted, but never compelled, to institute an IPR proceeding."). When considering whether to exercise this discretion, we look to factors, including:

1. whether the petitioner filed a prior petition directed to the same claims of the same patent;

2. whether the petitioner filed the subsequent petition after the petitioner received the patent owner's preliminary response to the prior petition or the Board's institution decision on the prior petition;

¹ U.S. Patent No. 4,454,657, issued June 19, 1984 (Ex. 1203, "Yasumi").

² U.S. Patent No. 5,437,083, issued August 1, 1995 (Ex. 1227, "Williams").

³ U.S. Patent No. 6,051,002, issued April 18, 2000 (Ex. 1218, "Morales 2").

3. whether the petitioner knew, or should have known, of the references newly asserted in the subsequent petition when the petitioner filed the prior petition, and the length of time from when the petitioner learned of the references newly asserted in the subsequent petition to when the subsequent petition was filed;

4. whether the petitioner provided an adequate explanation for the time elapsed between filing the prior petition and the subsequent petition; and

5. whether the subsequent petition weighs on the finite resources of the Board and the requirement, absent good cause, to issue a final determination not later than one year after the date on which the Director notices institution of review.

See Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, IPR2016-01357 (PTAB Sept. 6, 2017) (Paper 19, 15–16) (informative) ("Gen. Plastic").

In applying these factors, we consider not only the congressional intent that *inter partes* review proceedings provide an effective and efficient alternative to district court litigation, but also the potential for abuse of the review process through repeated attacks by the same petitioner with respect to the same patent. *See Gen. Plastic*, slip. op. at 16–17 (citing H.R. Rep. No. 112-98, pt.1, at 40 (2011)). We address each of these factors in turn, but note that not all the factors need to weigh against institution for us to exercise our discretion under § 314(a).

<u>Whether Petitioner Previously Filed a Petition Directed to the Same Claims</u> of the Same Patent

The Challenged Claims of the '560 patent that are the subject of the Petition are the same claims of the same patent that Petitioner challenged in its prior petitions in IPR-072 and IPR-444. IPR-072 Petition, 44–93; IPR-444 Petition, 49–97. Accordingly, this factor weighs against institution. <u>Whether the Petition Was Filed after Petitioner Received Patent Owner's</u> <u>Preliminary Response to the Prior Petition or the Board's Institution</u> Decision on the Prior Petition

In IPR-072, Patent Owner's preliminary response was filed on January 25, 2017. IPR-072, Paper 7, 45. In IPR-444, Patent Owner's preliminary response was filed on April 4, 2017. IPR-444, Paper 7, 45. Accordingly, when Petitioner filed the Petition in this case on April 19, 2017, Petitioner had Patent Owner's preliminary responses addressing the prior petition in IPR-072 for nearly three months and the prior petition in IPR-444 for over two weeks.

Although Petitioner did not have either our decision declining institution of *inter partes* review in IPR-072 or our decision instituting *inter partes* review in IPR-444 prior to filing the Petition, Petitioner had ample time to take advantage of Patent Owner's Preliminary Responses to the prior petitions in crafting its arguments in the Petition. Indeed, the Petition suggests the grounds asserted in this case are intended to overcome arguments made by Patent Owner in response to the prior petitions. *See* Pet. 93–94 (Petitioner stating, for example, that Patent Owner's argument in response to prior petition that alleged applicant admitted prior art is not prior art is inapplicable to Williams in this case). Consequently, this factor weighs against institution.

<u>Whether Petitioner Knew, or Should Have Known, of the References</u> <u>Asserted in the Petition When It Filed the Prior Petition and the Length of</u> <u>Time Between Learning of the References and Filing the Petition</u>

Petitioner contends the Challenged Claims of the '560 patent would have been obvious over Yasumi and Williams, with the addition of Morales 2 for certain claims. Pet. 26–27. Petitioner's contentions in IPR-444 also relied on Yasumi. IPR-444 Petition, 30. Williams and Morales 2 are both expressly identified in the '560 patent. Ex. 1201, References Cited. Thus, Petitioner knew or should have known of Yasumi, Williams, and Morales when it filed the prior petition in IPR-444.

Petitioner's filing of the Petition on April 18, 2017, in this case reflects a delay in excess of six months from when the prior petition was filed in IPR-072, and a delay in excess of four months from when the prior petition was filed in IPR-444. Accordingly, because Petitioner knew or should have known of the references it asserts in this case at least at the time it filed the prior petition in IPR-444, but waited over four months to file a third petition, this factor weighs against institution.

<u>Whether Petitioner Provided an Adequate Explanation for the Time Elapsed</u> <u>Between Filing the Petitions</u>

Petitioner does not provide a persuasive explanation for the time elapsed between filing the prior petitions in IPR-072 and IPR-444 and filing the Petition in this case. Petitioner primarily argues only that the grounds asserted in the Petition are not redundant to grounds asserted in the earlier petitions. Pet. 93–94. Even if the grounds asserted in the third petition are materially different from grounds asserted in the prior petitions, that does not explain or justify Petitioner's decision to wait to file the subsequent petition on references Petitioner knew, or should have known of, when the prior petition was filed. In particular, Petitioner provides no explanation for its delay in relying on a reference in place of purported applicant admitted prior art when Patent Owner first raised its argument on that issue in its preliminary response in IPR-072 on January 25, 2017. IPR-072, Paper 7, 7– 11. Consequently, this factor also weighs against institution.

Board Resources and Issuance of a Final Determination

Analysis of "multiple, staggered petition filings" is, in general, "an inefficient use of the *inter partes* review process and the Board's resources." *Gen. Plastic*, slip. op. 21. The final hearing in IPR-444 is scheduled for March 15, 2018. Proceeding with multiple challenges by the same Petitioner to the same patent on different schedules presents a burden on both Patent Owner and the Board, particularly in the absence of any reasoning from Petitioner for the substantial delay between filing the petitions. *See* IPR-444, Paper 8, 8. Thus, we consider this factor to favor non-institution.

B. Conclusion

For the reasons discussed above, we find that the factors we consider in determining whether to exercise our discretion not to institute an *inter partes* review favor non-institution in this case. Thus, we exercise our discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a) not to institute review with respect to claims 1, 2, 6, 8–11, 14, 15, 17–19, 23, 25–28, 31, 33–35, 37, 39, and 40 of the '560 patent in this case.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '560 patent, and no trial is instituted.

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Petitioner

Craig S. Summers Brenton R. Babcock Christy G. Lea Cheryl T. Burgess KNOBBE, MARTENS, OLSON & BEAR 2css@knobbe.com 2brb@knobbe.com 2cgl@knobbe.com 2ctb@knobbe.com

Patent Owner

Wallace Wu Jennifer A. Sklenar Nicholas M. Nyemah ARNOLD & PORTER KAYE SCHOLER LLP xEDW_BSC_IPR01301@apks.co