Trials@uspto.gov
571-272-7822

Paper 12
Entered: February 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOCON PHARMA LIMITED,
Petitioner,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

IPR2020-01263
Patent 8,101,659 B2

Before ERICA A. FRANKLIN, ROBERT A. POLLOCK, and KRISTI L. R. SAWERT, *Administrative Patent Judges.*

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. §§ 314, 325(d)

I. INTRODUCTION

Biocon Pharma Limited ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–4 of U.S. Patent No. 8,101,659 B2 (Ex. 1001, "the '659 patent") pursuant to 35 U.S.C. § 311. Novartis Pharmaceuticals Corporation ("Patent Owner") timely filed a Preliminary Response (Paper 7, "Prelim. Resp."). On our authorization (Paper 9, "Order"), Petitioner filed a preliminary Reply (Paper 10, "Reply") and Patent Owner filed a preliminary Sur-Reply (Paper 11, "Sur-Reply").

We have the authority and discretion to determine whether to institute an *inter partes* review. 35 U.S.C. § 314; 37 C.F.R. § 42.4. We may not institute an *inter partes* review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). After considering the Petition, Preliminary Response, Reply, and Sur-Reply, as well as the associated evidence, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. §325(d).

II. BACKGROUND

A. Real Parties-In-Interest

Petitioner identifies Biocon Limited, Biocon Pharma Limited, and Biocon Pharma, Inc. as the real parties-in-interest. Pet. 70. Patent Owner identifies Novartis Pharmaceuticals Corporation as the real party-in-interest. Paper 6, 1.

B. Related Matters

Petitioner and Patent Owner state the '659 patent has been, or is, at issue in several judicial proceedings. Pet. 7–9; Paper 6, 1. Patent Owner specifically identifies the following judicial proceedings as related matters: (1) *In Re: Entresto (Sacubitril/Valsartan) Patent Litig.*, No. 20-md-2930-

LPS; (2) *Novartis Pharm. Corp. v. Alkem Labs. Ltd.*, No. 19-cv-1979-LPS (D. Del.); (3) *Novartis Pharm. Corp. v. Alembic Pharm. Ltd.*, No. 19-cv-2021-LPS (D. Del.); (4) *Novartis Pharm. Corp. v. Dr. Reddy's Labs., Inc.*, No. 19-cv-2053-LPS (D. Del.); (5) *Novartis Pharm. Corp. v. Alembic Pharm. Ltd.*, No. 20-cv-74-LPS (D. Del.); (6) *Novartis Pharm. Corp. v. Lupin Atlantis Holdings, S.A.*, No. 20-cv-415-LPS (D. Del.); (7) *Novartis Pharm. Corp. v. Mylan Pharm. Inc.*, No. 20-cv-445-LPS (D. Del.); (8) *Novartis Pharm. Corp. v. Mylan Pharm. Inc.*, No. 19-cv-201-IMK (N.D. W.Va.); and (9) *Novartis Pharm. Corp. v. Macleods Pharm. Ltd.*, No. 19-cv-19345 (D.N.J.) (dismissed). Paper 6, 1.

C. The '659 Patent (Ex. 1001)

The '659 patent, titled "Methods of Treatment and Pharmaceutical Composition," issued January 24, 2012, based on an application filed June 27, 2008. Ex. 1001, codes (22), (45), (54). The '659 patent relates to a pharmaceutical composition comprising valsartan and an NEP inhibitor, namely, N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester ("sacubitril") or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid. *Id.* at 3:19–22, 16:16–25. Valsartan is an AT 1-receptor antagonist. According to the '659 patent, AT 1-receptor antagonists "can be used, e.g., as anti-hypertensive's [*sic*] or for the treatment of congestive heart failure, among other conditions." *Id.* at 1:49–51. NEP inhibitors "lower blood pressure and exert ANF-like effects, such as diuresis and increased cyclic guanosine 3′,5′-monophosphate (cGMP) excretion." *Id.* at 2:39–43.[1]

[1] The written description of the '659 patent explains that ANFs (atrial natriuretic factors), "also known as ANPs, brain natriuretic peptide (BNP), met and leu enkephalin, bradykinin, neurokinin A and substance P . . . . are a

The '659 patent states that "combination therapy with valsartan and a NEP inhibitor results in a more effective anti-hypertensive therapy . . . through improved efficacy, as well as a greater responder rate." *Id.* at 6:65–7:3. In particular, the '659 patent states that "[i]t has surprisingly been found that, a combination of valsartan and a NEP inhibitor achieves greater therapeutic effect than the administration of valsartan, ACE inhibitors or NEP inhibitors alone and promotes less angioedema than is seen with the administration of a vasopeptidase inhibitor alone." *Id.* at 6:41–45. The '659 patent states that the combination therapy "is also useful in the treatment or prevention of heart failure." *Id.* at 7:3–4.

D. Illustrative Claim

Of the challenged claims, claim 1 is independent. Ex. 1001, 16:16–33. Claims 2–4 depend, directly or indirectly, from claim 1. *Id.* at 16:34–47. Claim 1, reproduced below, illustrates the claimed subject matter:

> 1. A pharmaceutical composition comprising:
>
> (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;
>
> (ii) the NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-biphenyl-4-yl-4(3-carboxy-propionyl amino)-2-methyl-pentanoic acid or a pharmaceutically acceptable salt thereof, and
>
> (iii) a pharmaceutically acceptable carrier;
>
> wherein said (i) AT 1-antagonist valsartan or pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor N-(3-carboxy-1-oxopropyl)-(4S)-(p-phenylphenylmethyl)-4-amino-2R-methylbutanoic acid ethyl ester or (2R,4S)-5-

---

family of vasodilator, diuretic and anti-hypertensive peptides," and among the substrates for the zinc-metalloprotease, NEP (neutral endopeptidase). *Id.* at 2:10–21.

> biphenyl-4-yl-4(3-carboxy-propionylamino)-2-methyl-pentanoic acid or pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio.

Id. at 16:16–33.

E. Asserted Evidence

Petitioner submits the following evidence:

Evidence	**Exhibit No.**
EP 0 726 072 A2 (published Aug. 14, 1996) ("EP '072")	1002
Shetty and DelGrande, *Differential Inhibition of the Prejunctional Actions of Angiotensin II in Rat Atria by Valsartan, Irbesartan, Eprosartan, and Losartan*, J. PHARMACOL. EXP. THER. 294:179–186 (2000) ("Shetty")	1004
Gomez-Monterrey et al., *New Thiol Inhibitors of Neutral Endopeptidase EC 3.4.24.11: Synthesis and Enzyme Active-Site Recognition*, J. MED. CHEM. 37:1865–1873 (1994) ("Gomez-Monterrey")	1005
Ksander et al., *Dicarboxylic Acid Dipeptide Neutral Endopeptidase Inhibitors*, J. MED. CHEM. 38:1689–1700 (1995) ("Ksander")	1006
U.S. Pat. No. 5,217,996 (issued June 8, 1993) ("the '996 patent")	1009
Physicians' Desk Reference, Edition 54 (2000) ("PDR").	1012
Declaration of Y.W. Francis Lam, Pharm.D.	1018

F. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–4 are unpatentable under 35 U.S.C. § 103(a)[2] based on the following grounds:

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended several provisions of 35 U.S.C., including § 103. Because the '659 patent claims priority to an application that has an effective filing date prior to the effective date of the applicable AIA amendments, we refer herein to the pre-AIA version of § 103.

Claims Challenged	35 U.S.C. §	References/Basis
1–4	103(a)	EP ’072, Shetty, Gomez-Monterrey, Ksander
1–4	103(a)	PDR, the ’996 patent, Gomez-Monterrey, EP ’072

Pet. 14.

III. DISCRETION UNDER 35 U.S.C. § 325(d)

Section 325(d) provides that the Director may elect not to institute a proceeding if the challenge to the patent is based on matters previously presented to the Office. *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7 (PTAB Feb. 13, 2020) (precedential) (“*Advanced Bionics*”).[3] In evaluating matters under § 325(d), the Board uses the following two-part framework: (1) determining whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of the first part of the framework is satisfied, determining whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims. *Id.* at 8.

We consider several non-exclusive factors as set forth in *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”), which “provide useful insight into how to apply the framework” under § 325(d). *Advanced Bionics*, 9. These non-exclusive factors include:

[3] The Board institutes trial on behalf of the Director. 37 C.F.R. § 42.4(a); *Advanced Bionics*, 7 n.7.

> (a) the similarities and material differences between the asserted art and the prior art involved during examination;
>
> (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
>
> (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
>
> (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
>
> (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
>
> (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, 17–18 (formatting added). "If, after review of factors (a), (b), and (d), it is determined that the same or substantially the same art or arguments previously were presented to the Office, then factors (c), (e), and (f) relate to whether the petitioner has demonstrated a material error by the Office." *Advanced Bionics*, 10.

Patent Owner argues that we should exercise our discretion under § 325(d) and deny institution. Prelim. Resp. 22–38; Sur-Reply 1–3. Petitioner opposes. Pet. 64–67; Reply 1–3. Upon consideration of the parties' respective arguments, discussed in detail below, and the relevant *Becton, Dickinson* factors as applied to the record in this case, we find that the factors weigh in favor of exercising our discretion under § 325(d). Thus, pursuant to the Board's precedent set forth in *Advanced Bionics*, we deny institution of the Petition for *inter partes* review.

A. Becton, Dickinson Factors (a), (b), and (d)

Becton, Dickinson factors (a), (b), and (d) relate to whether the same or substantially the same art or arguments were presented previously to the

Office. *Advanced Bionics*, 10. Petitioner contends that "[t]he Examiner never put forth any rejection as outlined in this Petition." Pet. 64. As noted above, Petitioner's grounds of unpatentability rely on prior-art references EP '072, Shetty, Gomez-Monterrey, and Ksander in the first ground, and PDR, the '996 patent, Gomez-Monterrey, and EP '072 in the second ground. Pet. 14. Petitioner contends that prior-art references PDR, Shetty, Gomez-Monterrey, and Ksander were not before the Examiner during prosecution. *Id.* Petitioner acknowledges that the remaining prior-art references (i.e., EP '072 and the '996 patent) were disclosed to the Examiner during prosecution of the application leading to the '659 patent, but contends that the Board "has consistently declined to exercise its discretion under § 325(d) based on the mere citation of references in an [Information Disclosure Statement (IDS)] that were not applied by the Examiner." *Id.* at 64 (quoting *Apotex, Inc. v. UCB Biopharma, SPRL*, IPR2019-00400, Paper 17 at 24 (PTAB July 15, 2019)). Petitioner also contends that its grounds of unpatentability set forth "specific arguments and rationales" that were not before the Examiner. Reply 1.

Patent Owner, in contrast, argues that "[t]he Examiner considered substantially the same art and/or arguments during prosecution." Prelim. Resp. 23. Patent Owner argues that EP '072 and the '996 patent were before the Examiner during prosecution, and that the Petition's remaining prior-art references (i.e., PDR, Shetty, Gomez-Monterrey, and Ksander) are merely cumulative to the prior-art references the Examiner applied during prosecution. *Id.* at 23–25; Sur-Reply 1. Patent Owner also argues that Petitioner's grounds of unpatentability are based on the same arguments that led the Examiner to twice reject the claims of the application leading to the '659 patent for *prima facie* obviousness. Prelim. Resp. 23–25.

Upon consideration of the parties' respective arguments and the prosecution history of the '659 patent, we find that Patent Owner has the better position. In particular, we agree with Patent Owner that the Petition advances the same or substantially the same art that was presented previously to the Office.[4]

Both EP '072 and the '996 patent were presented previously to the Office during prosecution. The record shows that the Examiner signed an IDS listing both EP '072 and the '996 patent. Ex. 1010, 89–90. The IDS also states that the Examiner considered both prior-art references. *Id.* In light of the Board's precedential *Advanced Bionics* decision, we reject Petitioner's contention that, even though EP '072 appears on an IDS, we should decline to exercise discretion under § 325(d) because EP '072 was "not applied by the Examiner." Pet. 64. As explained in *Advanced Bionics,* "[p]reviously presented art includes art made of record . . . such as on an Information Disclosure Statement (IDS)." *Advanced Bionics*, 7–8. Thus, we accept that the Examiner considered EP '072 because it is listed on the IDS and the Examiner signed the IDS with the statement "all references considered except where lined through." Ex. 1010, 90.

Turning to the remaining prior-art references that constitute Petitioner's grounds of unpatentability (i.e., PDR, Shetty, Gomez-Monterrey, and Ksander), we agree with Patent Owner that these references are cumulative, and thus substantially similar, to the art presented previously

[4] Because we determine that the "same or substantially the same prior art" was presented previously to the Office, we need not reach whether the "same or substantially the same arguments" were presented previously to the Office. *Advanced Bionics*, 20.

to the Office. During prosecution, the Examiner relied on U.S. Patent No. 5,339,578 ("the '578 patent," Ex. 1008) for teaching the AT 1-antagonist valsartan as an anti-hypertensive treatment, and on the '996 patent for teaching the NEP inhibitor sacubitril as an anti-hypertensive treatment. *See, e.g.*, Ex. 1010, 84–85. The Examiner determined that "employ[ing] combinations of a specific NEP inhibitor and valsartan would have been obvious because all the components are well known individually for treating hypertension." *Id.* at 85.

In its first ground of unpatentability, Petitioner relies on EP '072 for teaching a combination of AT 1-antagonist irbesartan and NEP inhibitor SQ 28603. Pet. 1–2. Petitioner relies on Shetty for teaching the effectiveness of valsartan as an AT 1-antagonist, *id.* at 2, 20–22, 29, on Ksander for teaching the effectiveness of sacubitril (i.e., "compound 19a") as an NEP inhibitor, *id.* at 3–4, 32–36, and on Gomez-Monterrey for teaching the relative ineffectiveness of SQ 28603, *id.* at 3, 31–32. Put differently, Petitioner begins with the teachings of EP '072, already before the Office, and relies on Shetty to substitute the claimed valsartan for EP '072's irbesartan and on Ksander and Gomez-Monterrey to substitute the claimed sacubitril for EP '072's SQ 28603. *Id.* at 1–3. In its second ground of unpatentability, Petitioner relies on PDR for teaching valsartan as a specific AT 1-antagonist. *Id.* at 26, 46.

The use of valsartan as an AT 1-antagonist, however, was already provided in the teachings of the '578 patent and the use of sacubitril as a NEP inhibitor was disclosed in the '996 patent. Ex. 1010, 84–85, 170–172, 195–197. EP '072— teaching the combination of an AT 1-antagonist and an NEP inhibitor—was also presented previously to the Office. Thus, we agree with Patent Owner that PDR, Shetty, Gomez-Monterrey, and Ksander do not

provide any additional information relevant to the claim limitations at issue that was not already presented to, and considered by, the Office. Sur-Reply 1. For these reasons, we determine that the Petition presents the same or substantially the same art previously presented to the Office. *Advanced Bionics*, 10.

B. Becton, Dickinson Factors (c), (e), and (f)

Because the first part of the *Advanced Bionics* two-part framework is satisfied, we now turn to *Becton, Dickinson* factors (c), (e), and (f)—that is, "whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of [the] challenged claims." *Advanced Bionics*, 8. According to *Advanced Bionics*, for the second part of the two-part framework, "[i]f . . . the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review." *Advanced Bionics*, 8–9.

Petitioner contends that "the Examiner overlooked the specific teaching of EP '072 causing material error." Pet. 65. In particular, Petitioner contends that, during prosecution, the Examiner allowed the claims of the '659 patent only upon a showing of experimental data in the Webb Declaration[5] of a synergistic effect from the combination of valsartan and a specific NEP inhibitor. *Id.* at 66. Petitioner highlights the Examiner's statement in the Reasons for Allowance that "the experimental data showing that the combination of valsartan and the specific NEP inhibitor (AH377) has a synergistic, unexpected and surprising antihypertensive effect . . . is not taught or obvious from the prior art." *Id.* (quoting Ex. 1010, 240). "Had

[5] *See* Declaration under 37 C.F.R. § 1.132 ("the Webb Declaration"). Ex. 1015, 884–919.

the Examiner reviewed EP '072," Petitioner contends, "the Examiner would have noted that the alleged unexpected results reported in the Webb Declaration of the '659 patent are the exact same results taught by EP '072." *Id*.

In this respect, Petitioner contends that EP '072 "teaches that a combination of an AT 1-antagonist (i.e., irbesartan) and a NEP inhibitor (i.e., SQ 28603) produced synergistic effects, i.e., significant reductions in both Left Ventricular End Diastolic Pressure (LVEDP) and Left Ventricular Systolic Pressure (LVSP) that were greater than those produced by either treatment alone." Pet. 61 (citing Ex. 1002, 2:29–31, 9:22–23). Petitioner also contends that "EP '072 even expressly refers to the effect of the addition of these two active classes as acting 'synergistically.'" *Id.* at 61 (quoting Ex. 1002, 2:27; citing Ex. 1008 ¶ 232). "Since the Examiner was convinced that the alleged synergistic effect" shown in the Webb Declaration was "'not taught or obvious from the cited prior art,'" Petitioner contends, "the only reasonable conclusion is the Examiner overlooked the specific teaching of EP '072 causing a material error." *Id.* at 65 (quoting Ex. 1010, 240).

Patent Owner argues that Petitioner "has not met its burden of showing the Office erred in a manner material to patentability in concluding the Webb Declaration synergistic antihypertensive results were unexpected over the prior art." PO Resp. 27. Patent Owner argues that Petitioner's reliance on Example 1(b) of EP '072 for a showing of synergy from the combination of an AT 1-antagonist and a NEP inhibitor is inapt because that example is not "directed to hypertension." *Id.* at 28. Instead, Patent Owner argues, EP '072's Example 2 shows "failed hypertension results [that]

further confirm the unexpectedness of the Webb Declaration data." *Id.* at 32.

Upon consideration of the parties' respective arguments and the prosecution history of the '659 patent, we again find that Patent Owner has the better position. As Patent Owner explains, EP '072 provides two examples testing the cardiovascular effects of a combination AT 1-antagonist and a NEP inhibitor that are relevant here: Example 1(b), describing the cardiovascular effect of BMS 186295 (i.e., irbesartan) and SQ 28603 (a NEP inhibitor) in "cardiomyopathic hamsters," Ex. 1002, 7:28–31, and Example 2, describing the cardiovascular effect of BMS 186295 and SQ 28603 "in dogs that had been rendered hypertensive by prior unilateral nephrectomy and construction of the remaining renal artery," *id.* at 9:31–32. In Example 1(b), EP '072 teaches that the combination of BMS 186295 and SQ 28603 produced synergistic "hemodynamic effects in cardiomyopathic hamsters in compensated heart failure":

> The combination of BMS 186295 and SQ 28603 produced cardiovascular effects that were greater than those with either treatment alone. Specifically, the combination caused significant decreases in left ventricular end diastolic pressure [LVEDP] and left ventricular systolic pressure [LVSP] with no significant change in heart rate.

Id. at 9:22–27. But, in Example 2, EP '072 teaches that, while BMS 186295 alone "reduced mean arterial pressure (MAP)" in hypertensive dogs, "[t]he effects of the combination BMS 186295 and SQ 28603 were not consistently different from those of [placebo]." *Id.* at 10:33–35.

The record supports Patent Owner's argument that Example 1(b) of EP '072 does not relate to hypertension, and thus, fails to show material error in the Examiner's consideration of the Webb Declaration. Prelim.

Resp. 28–31. As noted above, the Examiner allowed the claims of the '659 patent upon the showing of synergistic experimental results in the Webb Declaration. *See* Ex. 1010, 240 (Reasons for Allowance). The Webb Declaration provides experimental data that "the pharmaceutical combination of [sacubitril] and valsartan as claimed . . . has (i) synergy in lowering mean arterial pressure in animal models of hypertension as compared to monotherapy with either active agent alone." Ex. 1015, 885 ¶ 5. The Webb Declaration further states that "this synergy is an unexpected and surprising blood pressure lowering effect which would not be expected by one of ordinarily skill in the art." *Id.*

Although Petitioner relies on Example 1(b) of EP '072 for "expressly [teaching] *the same synergistic effect* when combining an AT 1-antagonist with a NEP inhibitor," Pet. 5 (emphasis added), we agree with Patent Owner that EP '072's synergistic effect is not, in fact, the same synergistic effect as that shown in the Webb Declaration. Specifically, EP '072 supports Patent Owner's argument that the cardiomyopathic hamsters utilized in Example 1(b) had *low* blood pressure and elevated levels of atrial natriuretic peptide (ANP), and thus, were a model for heart failure rather than hypertension. *See* Ex. 1002, 6:39–43 (teaching that cardiomyopathic hamsters are characterized (as compared with control hamsters) by low mean arterial pressure" and "an 8–10-fold increase in plasma natriuretic peptide concentration"); *see also* Prelim. Resp. 29. With respect to high ANP levels specifically, other record evidence supports Patent Owner's argument that EP 072's cardiomyopathic hamsters are a model of heart failure. *See* Ex. 2003, Abstract (teaching that "[a]n elevated plasma concentration of atrial natriuretic peptide (ANP) is characteristic of congestive heart failure

(CHF) in both humans and animals").[6] The elevated level of ANP in the cardiomyopathic hamsters contrasts with the "normal plasma concentrations" of ANP in the hypertensive dogs utilized in EP '072's Example 2.

In its Reply, Petitioner does not refute Patent Owner's argument that EP '072's Example 1(b) does not relate to hypertension. *See generally* Reply 2–3. Instead, Petitioner contends that, to the extent the Webb Declaration's "alleged unexpected results are only limited to an antihypertensive effect," these results "are *not* commensurate with the scope of the ['659 patent's] claims." *Id.* Petitioner points out that, of the '659 patent's four claims, claims 1, 3, and 4 "are *not* limited to any specific condition, whereas [c]laim 2 recites hypertension *or heart failure*." *Id.*

Although we have considered Petitioner's contentions, we are not persuaded that they show material error by the Examiner. Claims 1–4 of the '659 patent are composition claims. Reply 2; *see also* Ex. 1001, 16:17–47 (claims 1–4 directed to a "pharmaceutical composition"). As Patent Owner argues, and we agree, "[f]or such claims, showing unexpected superiority for one property is sufficient to overcome a *prima facie* showing of obviousness." Reply 2 (citing *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987) ("Evidence that a compound is unexpectedly superior in one of a spectrum of common properties, as here, can be enough to rebut a *prima facie* case of obviousness.")). Here, the Examiner relied on unexpected synergistic results of an anti-hypertensive effect to allow the claims. Petitioner fails to show persuasively that the Examiner's reliance on those

[6] Smits, et al., *Effect of Endopeptidase 24.11 Inhibition in Conscious Cardiomyopathic Hamsters*, 254(1) J. PHARMACOL. EXP. THER. 176–179 (1990).

synergistic results for one property (i.e., anti-hypertensive effect) within the scope of the claims constitutes a material error under *Advanced Bionics*. Indeed, as the Federal Circuit has explained, "[o]bjective evidence of nonobviousness need only be reasonably commensurate with the scope of the claims, and we do not require a patentee to produce objective evidence of nonobviousness for every potential embodiment of the claim." *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013); *see also id.* (characterizing the Board's finding that patentee's evidence relating to high-speed memory systems was not commensurate with the scope of the claims because the claims did not recite a specific clock speed and therefore embraced slow memory devices as unduly "strict" and "improper").[7]

We are also persuaded by Patent Owner's argument that EP '072's Example 2 supports the Examiner's finding that the Webb Declaration's showing of synergistic anti-hypertensive effect from the combination of a NEP inhibitor and valsartan was unexpected over the prior art. Prelim. Resp. 32–35. Example 2 of EP '072 shows that, in a 1K1C dog model of hypertension, "[t]he effects of the combination BMS 186295 and SQ 28603 were not consistently different from those of [placebo]." Ex. 1002, 10:33–35. This contrasts with the Webb Declaration's showing that the combination of valsartan and sacubitril had an anti-hypertensive effect that was greater than the sum of the effect of valsartan alone plus that of sacubitril alone. *Compare* Ex. 1002, 10:33–35, *with* Ex. 1015, 891 ¶ 16. Petitioner does not address, or otherwise refute, Patent Owner's

[7] Petitioner also appears to suggest that Patent Owner misled the Examiner as to the full scope of the claims and/or the Webb Declaration. *See* Reply 2–3. These contentions are outside our jurisdiction and, thus, we do not consider them. 35 U.S.C. § 311(b).

characterization of the results of Example 2. *See generally* Reply. For these reasons, we find no material error in the Examiner's finding that the anti-hypertensive effect shown in the Webb Declaration was "not taught or obvious from the cited prior art." Ex. 1010, 240.

Petitioner also contends that we should not give weight to the Examiner's findings of synergism because the Webb Declaration fails to compare its "allegations of unexpected results . . . to the closest prior art," and because, "at best this improvement would be an improvement in degree, not in kind, and therefore . . . not probative of obviousness." Pet. 62 (citing Ex. 1018 ¶¶ 235–236). We are not persuaded. As to the former, we find that EP '072 does not support Petitioner's contention that "the combination of it AT 1-antagonist and a NEP inhibitor provides the same improvements over the monotherapy as alleged by Patent Owner to the Examiner" for the reasons explained immediately above. *Id.* As to the latter, we find that Petitioner does not provide persuasive evidence sufficient to support its contention that, in view of EP '072, the Webb Declaration shows only "an improvement in degree, not in kind, and therefore the alleged unexpected results are not probative of obviousness." *Id.* Although Petitioner cites to Dr. Lam's Declaration, Dr. Lam simply repeats Petitioner's argument without providing any underlying data. *See* Ex. 1018 ¶ 236. We also observe that Petitioner does not otherwise contend that the data presented in the Webb Declaration is inaccurate. *See* PO Resp. 29 ("[Petitioner] does not challenge that the Webb Declaration reported synergistic antihypertensive results"); *see also generally* Pet., Reply.

Finally, Petitioner contends that "relying on uncontested testimonial evidence from prosecution will not defeat an *inter partes* review for purposes of institution," and that "the Examiner did not have the benefit of

expert declaration of Dr. Lam explaining the art from the perspective of a [person having ordinary skill in the art]." Pet. 65–66; *see also* Reply 3 (stating that "the PTAB routinely defers detailed consideration of any objective indicia until after institution"). Although arguably relevant to *Becton, Dickinson* factor (f), we determine that neither of these contentions, even if true, outweigh Petitioner's failure in this proceeding to show material error in the Examiner's consideration of the Webb Declaration, as *Advanced Bionics* requires.

C. Summary

For the reasons discussed above, we exercise our discretion under 35 U.S.C. § 325(d) to deny institution of trial. As required by *Advanced Bionics*, we determine that the same or substantially the same art previously was presented to the Office and that Petitioner has not demonstrated that the Examiner erred when considering the prior art.

IV. CONCLUSION

For the foregoing reasons, we exercise our discretion to deny institution of *inter partes* review under 35 U.S.C. § 325(d).

V. ORDER

After due consideration of the record before us, and for the foregoing reasons, it is:

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

FOR PETITIONER:

Christopher Ferenc
Brian Sodikoff
KATTEN MUCHIN ROSENMAN LLP
christopher.ferenc@kattenlaw.com
brian.sodikoff@kattenlaw.com

FOR PATENT OWNER:

Nicholas N. Kallas
Christina Schwarz
VENABLE LLP
nkallas@Venable.com
cschwarz@venable.com