UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY
Petitioner

v.

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE
AT HARBOR-UCLA MEDICAL CENTER
Patent Owner

Case IPR2014-00752
Patent 8,133,903

PETITIONER ELI LILLY AND COMPANY'S
NOTICE OF APPEAL

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
Madison Building East, 10B20
600 Dulany Street
Alexandria, VA 22314-5793

Pursuant to 35 U.S.C. §§ 141 and 142 and 37 C.F.R. § 90.2, Petitioner Eli Lilly and Company hereby gives notice of its appeal to the United States Court of Appeals for the Federal Circuit from the February 8, 2018, Decision on Remand (Paper 53) by the United States Patent and Trademark Office Patent Trial and Appeal Board in *Inter Partes* Review IPR2014-00752, and from all orders, decisions, rulings, and opinions underlying the Decision on Remand. A copy of the Decision on Remand is attached as Exhibit A.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), the issues on appeal include, but are not limited to, the Board's erroneous determination that Petitioner has failed to demonstrate the unpatentability of claims 1-5 of U.S. Patent No. 8,133,903 under 35 U.S.C. § 103 (2010) by a preponderance of the evidence, including the Board's improper obviousness analysis and the absence of substantial evidence in support thereof; the Board's erroneous claim construction; the Board's violation of Petitioner's rights under the Administrative Procedure Act; and the Board's violation of Petitioner's due process rights and protections. Petitioner reserves the right to raise on appeal any finding or determination related to the

issues listed above and to raise any other issue decided adversely to the Petitioner in the proceedings underlying the Decision on Remand.

Pursuant to 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed with the Patent Trial and Appeal Board. In addition, a copy of this Notice and the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Date: April 9, 2018

Respectfully submitted,

/Mark J. Feldstein/

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CERTIFICATE OF SERVICE AND FILING

I hereby certify that on April 9, 2018, in addition to being filed and served electronically through the Patent Trial and Appeal Board's End to End System (PTAB E2E), a true and correct copy of the foregoing "PETITIONER ELI LILLY AND COMPANY'S NOTICE OF APPEAL" was filed by hand with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel, 10B20
Madison Building East
600 Dulany Street
Alexandria, Virginia

I also hereby certify that on April 9, 2019, a true and correct copy of the foregoing "PETITIONER ELI LILLY AND COMPANY'S NOTICE OF APPEAL," and the filing fee, were filed with the Clerk's Office of the United States Court of Appeals for the Federal Circuit, via CM/ECF.

I also hereby certify that on April 9, 2018, a true and correct copy of the foregoing "PETITIONER ELI LILLY AND COMPANY'S NOTICE OF APPEAL" was served, by electronic mail, upon the following counsel of record for the Patent Owner:

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Respectfully submitted,

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EXHIBIT A

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Paper 53
Date: February 8, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY,
Petitioner,

v.

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE
AT HARBOR-UCLA MEDICAL CENTER,
Patent Owner.

Case IPR2014-00752
Patent 8,133,903 B2

Before LORA M. GREEN, FRANCISCO C. PRATS, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON REMAND
35 U.S.C. § 144 and 37 C.F.R. § 42.5(a)

BACKGROUND

Petitioner, Eli Lilly and Company ("Eli Lilly" or "Petitioner"), filed a Petition requesting *inter partes* review of claims 1–5 ("the challenged claims") of U.S. Patent No. 8,133,903 B2 ("the '903 patent"). Paper 1 ("Pet."). Patent Owner, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center ("LA Biomed" or "Patent Owner"), filed a Patent Owner Preliminary Response. Paper 11 ("Prelim. Resp."). On the basis of the Petition and the Preliminary Response, we determined that Petitioner had demonstrated a reasonable likelihood of prevailing with respect to at least one of the challenged claims, and on October 23, 2014, an *inter partes* review of claims 1–5 was instituted on the asserted ground that the claims would have been unpatentable over the combined teachings of Montorsi,[1] Whitaker,[2] and Porst.[3] Paper 13, 16. After institution of trial, Patent Owner filed a Patent Owner Response (Paper 20), to which Petitioner filed a Reply (Paper 25). An oral hearing was held on June 16, 2015, and a transcript of the hearing has been entered into the record. Paper 43.

On October 22, 2015, we issued a Final Written Decision in accordance with 37 C.F.R. § 42.73. Paper 44 ("FWD"). We concluded that Petitioner had demonstrated by a preponderance of the evidence that claims

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[1] Francesco Montorsi et al. ("Montorsi"), *The Ageing Male and Erectile Dysfunction*, 20 WORLD J. UROL 28–35 (2002) (Ex. 1051).

[2] Whitaker et al. ("Whitaker"), Pub. No. WO 01/80860 A2, published Nov. 1, 2001 (Ex. 1086).

[3] Hartmut Porst et al. ("Porst"), *Daily IC351 Treatment of ED*, 20 INT'L J. IMPOT. RES. (SUPPL. 3) S76, Abstract B13 (2000) (Ex. 1096).

1–5 are unpatentable. *Id.* at 30. Patent Owner appealed the Final Written Decision to the United States Court of Appeals for the Federal Circuit.

The Federal Circuit issued a decision on February 28, 2017; *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly and Company*, 849 F.3d 1049 (Fed. Cir. 2017) ("*LA Biomed*") (*See* Paper 46 (slip opinion)). The court held that several of our claim constructions were in error, as were some of our findings and conclusions as to obviousness. *Id.* at 1067–68. The court, therefore, vacated our finding of obviousness and remanded the case. *Id.* at 1068. The Federal Circuit's mandate issued on May 24, 2017. Paper 48.

A conference call was held with the parties on May 23, 2017, to discuss the procedure to be taken post-remand. We authorized Petitioner to file a fifteen-page brief, we authorized Patent Owner to file a fifteen-page opposition, and also authorized Petitioner authorization to file a five-page Reply. Paper 49 ("Order"), 7–8. In accordance with our Order, Petitioner filed its Opening Brief on Remand on June 12, 2017. Paper 50 ("Op. Br.). Patent Owner filed a Responsive Brief on Remand on June 26, 2017 (Paper 51 ("Res. Br.")), and Petitioner filed its Reply Brief on Remand on July 3, 2017 (Paper 52 ("Reply Br.")).

We have reviewed the record in light of the Federal Circuit's decision and the arguments of the parties made in their briefs on remand. For the reasons that follow, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that the combination of Montorsi, Whitaker, and Porst renders challenged claims 1–5 of the '903 patent unpatentable under 35 U.S.C. § 103(a).

ANALYSIS

A. The '903 Patent

The '903 patent issued on March 13, 2011, with Nestor F. Gonzalez-Cadavid and Jacob Rajfer as the listed co-inventors. Ex. 1001. The '903 patent relates to methods of treating fibrotic conditions, such as Peyronie's disease ("PD"), with phosphodiesterase ("PDE") inhibitors, (*e.g.* sildenafil). *Id.* at 1:20–27. PD affects the tunica albuginea, which is the specialized lining of the corpora cavernosa of the penis, and clinically leads to penile deformation, pain, and erectile dysfunction ("ED"). *Id.* at 1:29–34. A PDE5 inhibitor, which selectively inhibits an isoform of PDE, is administered at a dosage up to 1.5 mg/kg/day, wherein the upper dosage is roughly equivalent to the dose ingested by men with an on-demand single 100 mg tablet. *Id.* at 2:62–2:64, 45:7–12.

The '903 patent teaches further that fibrotic disease is not limited to the reproductive organs, but can affect other tissues, such as cardiovascular tissues, noting that "[b]oth erectile dysfunction . . . and cardiovascular disease, particularly hypertension, are prevalent in the aging male." *Id.* at 2:8–12. An underlying cause of hypertension is arteriosclerosis due to an acquired fibrosis of the media of the arterial wall. *Id.* at 2:13–15. Thus, according to the '903 patent, "[a] need exists for effective methods to treat and/or ameliorate the symptoms of a variety of fibrotic disease, such as PD, ED and arteriosclerosis. No effective method of treatment currently exists that is directed towards the molecular pathways underlying excessive collagen deposition." *Id.* at 2:42–46.

According to the '903 patent:

> A distinction exists between long-term (weeks, months, years) continuous treatment with, for example, a PDE5 inhibitor such as sildenafil to maintain a constant level of these agents in order to arrest or regress a fibrotic condition, versus on demand (prior to the sexual act) single pill, short-term treatment with sildenafil or other PDE5 inhibitors to obtain smooth muscle vasodilation in the penis (male penile erection) or vagina/clitoris (female sexual arousal) upon sexual stimulation. Current studies with sildenafil are symptomatic to treat defects in vaginal/clitoral or penile vasodilation exclusively during a sexual act and are not addressed to the long-term cure of underlying tissue fibrosis.

Id. at 10:59–11:3.

The '903 patent teaches also that there is an increase in collagen fibers, and, thus, an intensification, of fibrosis in the aging man. *Id.* at 46:5–43 (Example 16, "Intensification of Aging-Related Fibrosis in the Arterial Media by iNOS Inhibition"). According to the '903 patent,

> the prevalence of ED and hypertension in man seems to parallel each other as a function of age, and many disorders that damage one of these vascular tissues also seem to impact the other e.g. diabetes, chronic renal failure, etc. In all these disorders, vascular oxidative stress and fibrosis, leading to arteriosclerosis, are common denominators at the histological and molecular and levels.

Id. at 48:47–54 (references removed).

B. Illustrative Claim

Of challenged claims 1–5, claim 1 is independent, is illustrative of the claimed subject matter, and is reproduced below:

> 1. A method comprising:
>
> a) administering a cyclic guanosine 3′, 5′-monophosphate (cGMP) type 5 phosphodiesterase (PDE 5) inhibitor according

> to a continuous long-term regimen to an individual with at least one of a penile tunical fibrosis and corporal tissue fibrosis; and
>
> b) arresting or regressing the at least one of the penile tissue fibrosis and corporal tissue fibrosis, wherein the PDE-5 inhibitor is administered at a dosage up to 1.5 mg/kg/day for not less than 45 days.

Ex. 1001, 68:23–32.

C. The Final Written Decision

In the Final Written Decision, we construed multiple claim terms. FWD 5–9. In particular, as to the claim requirement of a "continuous long-term regimen," we noted that "delivering a PDE5 inhibitor at a dosage up to 1.5 mg/kg/day for at least 45 days would meet the claim requirement of a continuous, long-term regimen." *Id.* at 7. As to the requirement that the PDE-5 inhibitor is administered "at a dosage up to 1.5 mg/kg/day for not less than 45 days," we concluded "administering a dosage up to 1.5 mg/kg/day for at least 45 days would, according to the language of the claim, meet the limitation of a 'continuous, long-term regimen,' as well as result in 'arresting or regressing the at least one of the penile tunical fibrosis and corporal tissue fibrosis,' as recited by claim 1." *Id.* at 9.

We construed "an individual with at least one of a penile tunical fibrosis and corporal tissue fibrosis" as requiring "that the individual have symptoms that may be associated with penile fibrosis, such as ED, but not that the patient be specifically diagnosed as having penile tunical fibrosis or corporal tissue fibrosis." *Id.* at 7–8. And finally, we construed the claim limitation of "arresting or regressing the at least one of the penile tissue fibrosis and corporal tissue fibrosis" as "the intended result of administering a PDE5 inhibitor at a dosage up to 1.5 mg/kg/day for at least 45 days." *Id.* at 8–9.

In addressing the merits of the obviousness challenge, we reviewed the teachings of Montorsi, Whitaker, and Porst. FWD 14–18. After summarizing the teachings of those references, we noted:

> Claims 1–5 encompass a method of administering a PDE5 inhibitor, at a dosage up to 1.5 mg/kg/day for not less than 45 days, to an individual with a corporal tissue fibrosis, e.g., corporal veno-occlussive dysfunction ("CVOD"), such that the fibrosis is arrested or regresses. As noted above in the section discussing claim construction, arresting or regressing the fibrosis is the intended result of administering a PDE5 inhibitor, at a dosage up to 1.5 mg/kg/day for not less than 45 days. In addition, the claim does not require a diagnosis of penile tunical fibrosis or corporal tissue fibrosis, but encompasses treatment of a patient presenting with symptoms that may be associated with fibrosis, such as ED in certain patient populations, as discussed below.

Id. at 18.

Based on the above claim construction, as well as the evidence and arguments presented by Petitioner, we determined that Petitioner had demonstrated by a preponderance of the evidence that the combination of Montorsi, Whitaker, and Porst rendered obvious claim 1 of the '903 patent. *Id.* at 20. Specifically, we concluded:

> As to the limitation that [an] individual has at least one of . . . penile tunical fibrosis or corporal tissue fibrosis, as construed above, that limitation does not require that the patient be specifically diagnosed as having penile tunical fibrosis or corporal tissue fibrosis, but has symptoms associated with penile fibrosis, such as ED. Montorsi specifically teaches treatment of ED in elderly patients, which Montorsi teaches is associated with the development of corporal fibrosis. Whitaker teaches treatment of ED in patent populations with diabetes, atherosclerosis, smoking, hypertension, or a combination of such factors. Montorsi ties atherosclerosis to the veno-occlusive mechanism of the corpora cavernosa. Thus, treatment

> of ED in elderly patients or patients with atherosclerosis, as suggested by both Montorsi and Whitaker, would result in treatment of patients with the fibrosis, as Montorsi teaches that corporal fibrosis is associated with ED in those patient populations.

Id. at 22. In coming to that conclusion, we rejected Patent Owner's argument that "it ***contradicted*** the scientific community's belief regarding the role of iNOS in fibrosis." *Id.* (quoting PO Resp. 33). Specifically, we opined that Patent Owner was arguing the mechanism of action underlying penile fibrosis, and that as the language of the claim does not require any impact on iNOS or cGMP levels, any impact on those levels that would result from the administration of PDE5 inhibitors would be inherent in the method of claim 1. *Id.*

Patent Owner argued further that the references, either alone or as combined, did not teach or suggest treating an individual with either tunical or corporal fibrosis, asserting that not all patients suffering from erectile dysfunction also have underlying tunical or corporal fibrosis. *Id.* at 23. We disagreed, finding that Montorsi teaches that atherosclerosis is associated with the veno-occlusive mechanism of the corpora cavernosa, and also teaches that corporal fibrosis is associated with ED in the aging male. *Id.* at 25. We determined, therefore, that the claimed method was obvious because Montorsi suggests treating the aging male with a PDE5 inhibitor, and both Montorsi and Whitaker suggest treating patients with ED associated with atherosclerosis with a PDE5 inhibitor. *Id.* Finally, as Patent Owner did not separately argue the patentability of dependent claims 2–5, we concluded that Petitioner had shown by a preponderance of the evidence that claims 1–5 are unpatentable under 35 U.S.C. § 103 over the combination of Montorsi, Whitaker, and Porst. *Id.* at 28.

D. The Decision of the Federal Circuit

On appeal to the Federal Circuit, a majority of the panel vacated and remanded our decision, with Judge Newman dissenting from the judgment. According to the majority opinion:

> Because the Board's obviousness determination was predicated on an erroneous claim construction of two of the limitations of claim 1, and because the Board did not make factual findings as to whether there was an apparent reason to combine the prior art references to treat penile fibrosis and whether a person of skill in the art would have had a reasonable expectation of success from such a combination, we remand this case to the Board. We also remand for the Board to make findings bearing on the obviousness of the "arresting or regressing" limitation.

LA Biomed, 849 F.3d at 1067–68.

Specifically, the Federal Circuit found our interpretation of the claim term "an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis" read that limitation out of the claim. *Id.* at 1059. The Federal Circuit noted that although erectile dysfunction may be a symptom of penile tunical fibrosis and corporal tissue fibrosis, "erectile dysfunction cannot be equated with tunical fibrosis and corporal tissue fibrosis." *Id.* Thus, the Federal Circuit concluded that the "broadest reasonable interpretation of the phrase 'an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis' is its plain meaning: an individual with penile tunical fibrosis and/or corporal tissue fibrosis." *Id.* (footnote omitted). Thus, according to the Federal Circuit, "the claims are narrower and are clearly aimed at penile fibrosis—not other types of fibrosis, and not at symptoms such as erectile dysfunction." *Id.* at 1060. The Federal Circuit concluded, however, that the penile tunical fibrosis and/or corporal tissue

fibrosis need not be clinically significant, stating that "[b]oth parties' experts agreed that some physicians would treat fibrosis even if it was not deemed 'clinically significant.'" *Id.*

As to the claim recitation of "arresting or regressing the at least one of the penile tunical fibrosis and corporal tissue fibrosis," the court determined that limitation required "halting the progression of, or reversing, penile fibrosis." *Id.* In particular, the Federal Circuit specified "that the phrase is more than a statement of the intended result of administering the PDE5 inhibitor within the dosage limits, with the frequency, and for at least the minimum period prescribed in the patent." *Id.* The wherein clause, that is, "wherein the PDE-5 inhibitor is administered at a dosage up to 1.5 mg/kg/day for not less than 45 days," only sets forth the minimum duration of treatment, but says nothing about efficacy. *Id.* at 1061. The "arresting and regressing" limitation, according to the Federal Circuit, "demands efficacy; the wherein clause does not." *Id.*

As to our obviousness analysis, the Federal Circuit determined that although we "concluded that the references on which [we] relied rendered obvious the treatment of erectile dysfunction via the claimed method, but [we] did not determine whether those references showed that it would have been obvious to use long-term continuous treatment with a PDE5 inhibitor to treat individuals with penile fibrosis and to achieve the arrest or regression of that condition." *Id.* at 1064. The Federal Circuit also determined that we did not find that the combination of Montorsi, Whitaker, and Porst taught "treating a patient with penile tunical fibrosis or corporal tissue fibrosis," or that the combination "provided the basis for a reasonable expectation of success in treating those conditions." *Id.* Moreover, the Federal Circuit

concluded that we did not make any "findings as to whether any reference or combination of references rendered obvious the claim limitation 'arresting or regressing the at least one of a penile tunical fibrosis and corporal tissue fibrosis,' because [we] erroneously concluded that arresting or regressing fibrosis is an inherent effect of any regimen exceeding 45 days regardless of the dosage." *Id.* at 1067.

E. Briefing on Remand and Analysis

In authorizing briefing after remand, we noted that as to the claim construction of the claim limitation of "an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis," our understanding of the Federal Circuit's claim construction was that claim limitation required "a recognition that the patient have penile tunical fibrosis and/or corporal tissue fibrosis, that is, that condition needs to be diagnosed, but need not be clinically significant." Order 3.

On remand, Petitioner argues that, because the Federal Circuit concluded that the tunical fibrosis and/or corporal tissue fibrosis need not be clinically significant, it follows that under the broadest reasonable interpretation that diagnosis is also not required, as that would add ambiguity to the claim. Op. Br. 2. That is, Petitioner asserts, it is unclear how the condition would be diagnosed and by whom. *Id.* Petitioner asserts, therefore, that "reading-in a diagnosis requirement would be beyond the scope of the remand." *Id.* Although acknowledging that the Federal Circuit determined "that erectile dysfunction cannot be equated with or a proxy for penile fibrosis," Patent Owner apparently agrees with Petitioner on the construction of "an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis," arguing that although "the claims certainly

encompass individuals with a diagnosis of penile fibrosis or a clinically significant form of the disease, they are not limited to such individuals." Res. Br. 1–2.

The issue with Petitioner's and Patent Owner's proposed construction of "an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis" as not requiring that the person being treated actually have at least one of penile tunical fibrosis and corporal tissue fibrosis, is that the parties have not explained how that construction differs from the construction we set forth in our Final Written Decision, and which the Federal Circuit rejected. That is, in the Final Witten Decision, we construed "an individual with at least one of a penile tunical fibrosis and corporal tissue fibrosis" as requiring "that the individual have symptoms that may be associated with penile fibrosis, such as ED, but not that the patient be specifically diagnosed as having penile tunical fibrosis or corporal tissue fibrosis." FWD 8. Thus, in our Final Written Decision, we did not equate penile tunical fibrosis and corporal tissue fibrosis with erectile dysfunction, but only that the patient have symptoms of penile tunical fibrosis and corporal tissue fibrosis, such as erectile dysfunction. *Id*. Accordingly, and in view of the Federal Circuit's conclusion that the construction we adopted in our Final Written Decision was incorrect, and its determination that we read "an individual with at least one of penile tunical fibrosis and corporal tissue fibrosis" out of the claim (*LA Biomed* at 1059), we reject the claim constructions proposed by the parties.

Rather, we conclude that the Federal Circuit meant what it said. That is, the patient being administered the PDE5 inhibitor has to be "an individual with penile tunical fibrosis and/or corporal tissue fibrosis." *LA Biomed* at

1059. That construction by the Federal Circuit is consistent with its reliance on *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir. 2001) for the proposition that even though the Specification of the '903 patent mentions various fibrotic conditions and their symptoms, "the claims are narrower and are clearly aimed at penile fibrosis—not other types of fibrosis, and not at symptoms such as erectile dysfunction." *LA Biomed* at 1060. That is, "the ordinary meaning 'narrowly refers to . . . the underlying disorder itself." *Id.*

In response to Petitioner's argument (Op. Br. 2) that the Federal Circuit's determination that penile tunical fibrosis or corporal tissue fibrosis need not be clinically significant requires us to conclude that there is no requirement that it be recognized that the patient actually has penile tunical fibrosis and/or corporal tissue fibrosis, we note that the Federal Circuit stated that the experts of both parties agreed "that some physicians would treat fibrosis even if it was not deemed 'clinically significant.'" *LA Biomed* at 1060. That statement is consistent with the Federal Circuit's construction of "an individual with penile tunical fibrosis and/or corporal tissue fibrosis being "an individual with penile tunical fibrosis and/or corporal tissue fibrosis," even if the fibrosis is not "clinically significant." Thus, this argument by Petitioner does not convince us that the claim does not require that the patient being treated actually have penile tunical fibrosis and/or corporal tissue fibrosis.

As to the merits of the obviousness challenge, Petitioner contends that the combination of Montorsi, Whitaker, and Porst renders the method of the challenged claims obvious. Op. Br. 2. In particular, Petitioner asserts that the prior art teaches treating penile fibrosis. *Id.* at 3.

Petitioner asserts that "Montorsi and Whitaker are directed to treating patients having penile fibrosis with PDE5 inhibitors (Ex. 1051, 31; Ex. 1086, 13–14 of 53), and Porst teaches that daily PDE5 inhibitor doses were 'safe and generally well tolerated' (Ex. 1096, S76 (B13))." *Id.* Specifically, as to Montorsi, Petitioner asserts:

> Montorsi teaches treating patients having "cavernosal fibrosis and veno-occlusive dysfunction" (CVOD), which is a claimed penile fibrosis. (Ex. 1051, 30–31 (*e.g.*, "treat ED in the elderly patient" where "the ED from ageing is the result of atherosclerosis induced cavernosal ischaemia leading to cavernosal fibrosis and [CVOD]"); Ex. 1001, claim 3; Ex. 1089, ¶¶ 51-53, 60–65, 77; Ex. 1121, ¶¶ 62, 124–34; Paper 44, 14, 22 ("Montorsi ties atherosclerosis to the veno-occlusive mechanism of the corpora cavernosa."); Ex. 1008, 3-4 of 32; Ex. 1009, 8 of 12.)

Id. at 3–4.

Patent Owner responds that the Federal Circuit "rejected Lilly's primary argument on remand: that Montorsi's suggestion of 'further study investigating the possible dosage of sildenafil to be administered daily at bedtime' will result in treatment of individuals with penile fibrosis." Res. Br. 3 (citing Ex. 1051, 31; Op. Br. 3–4). Specifically, Patent Owner asserts that Montorsi's data was limited to "one-time administration of sildenafil at bedtime to determine its effect on nocturnal erection," and did not limit the patient population to patients having erectile dysfunction caused by underlying fibrosis, or even to aging or atherosclerotic patients that would have an increased likelihood of underlying fibrosis. *Id.* (citing Ex. 1051, 31; *LA Biomed* at 1065). Thus, Patent Owner asserts, "Montorsi at best teaches as-needed administration of PDE-5 inhibitors to individuals with erectile dysfunction." *Id.*

Moreover, Patent Owner contends, the Federal Circuit "held that while Whitaker teaches chronic PDE-5 inhibitor administration, it does so only as to individuals with erectile dysfunction." *Id.* According to Patent Owner, the Federal Circuit rejected Petitioner's assertion that Whitaker targets a narrower population of patients based on Whitaker's discussion of a vascular conditioning effect, contending that the Federal Circuit concluded "that Whitaker contains 'no data to support this 'vascular conditioning' causation theory,' and that the theory itself is speculation that cannot serve as an express or implicit teaching." *Id.* at 3–4 (citing *LA Biomed* at 1065–66; Ex. 1086, 33:22–27, 34:19–24, 37:18–24; Ex. 2023 ¶¶ 181–193, 34–60, 198).

We agree with Patent Owner that Petitioner is advocating a position that was rejected by the Federal Circuit in *LA Biomed*. According to Petitioner, Montorsi and Whitaker are directed to treating patients having penile fibrosis with PDE5 inhibitors. Op. Br. 3 (citing Ex. 1051, 31; Ex. 1086, 13–14 of 53). Specifically, as to Montorsi, we previously found that "Montorsi teaches that ED in the aging male is associated with the development of corporal fibrosis." FWD 20 (citing Ex. 1051, Abstract; *see also* Ex. 1051, 31 (noting that "it seems reasonable to hypothesize that the ED from ageing is the result of atherosclerosis-induced cavernosal ischemia leading to cavernosal fibrosis and veno-occlusive dysfunction.").

In its decision, the Federal Circuit, however, stated:

> To be sure, Montorsi teaches that corporal fibrosis is associated with erectile dysfunction in atherosclerotic or aging patient populations. Montorsi, however, is directed to on-demand dosing of PDE5 inhibitors; it does not teach long-term daily treatment. The only statement in Montorsi relating in any way to long-term treatment appears in Montorsi's discussion of

> a study showing that a onetime administration of sildenafil at bedtime increased nocturnal erections in men between 40 and 68 years of age with erectile dysfunction. Montorsi comments that the study "opened the door to further study investigating the possible dosage of sildenafil to be administered daily at bedtime." Montorsi at 31. The study discussed by Montorsi, however, was not limited to a population of patients suffering from erectile dysfunction caused by an underlying fibrotic condition (or even aging or atherosclerotic patients who have a higher likelihood of an underlying fibrosis).

LA Biomed at 1065. That is, the Federal Circuit concluded that although Montorsi teaches that erectile dysfunction is associated with corporal fibrosis in patients with atherosclerosis and in the aging male, Montorsi is directed to on-demand dosing, and not long term dosing. In addition, the Federal Circuit determined that the study discussed by Montorsi was not directed to patients with fibrosis, or even patients with atherosclerosis, who would be more likely to have underlying fibrosis. Rather, Montorsi taught that the results of the reported study

> show that sildenafil is an effective treatment for ED in elderly men with ED of various aetiologies and with concomitant illnesses. More than two-thirds of the men in the broad spectrum ED subgroup and one-half of the men in the ED and diabetes subgroup reported improved erections with sildenafil treatment.

Ex. 1051, 33.

Thus, Montorsi did not treat only patients with underlying fibrosis, did not identify patients with fibrosis, and did not report any effect that the PDE5 inhibitor sildenafil may have had on fibrosis. Instead, Montorsi reported that men with erectile dysfunction of various etiologies reported improved erections. Although Montorsi hypothesizes that erectile dysfunction in the ageing male may be due atherosclerosis-induced

cavernosal ischemia leading to cavernosal fibrosis and veno-occlusive dysfunction, Montorsi does not teach or suggest administering the PDE 5 inhibitor sildenafil to men who specifically have underlying penile tunical fibrosis and corporal tissue fibrosis.

Whitaker does not remedy that deficiency. In our Final Written Decision, we relied on Whitaker for teaching daily administration of a PDE5 inhibitor for as long as the erectile dysfunction lasts. FWD 20. In addition, we noted that Whitaker suggested that the chronic administration of a PDE5 inhibitor "may result in a 'partial or complete reversal of circulatory dysfunctions in penile circulation arising from conditions such as diabetes, atherosclerosis, smoking, hypertension, or a combination of such factors.'" *Id*. at 16 (quoting Ex. 1086, 13:11–16).

The Federal Circuit, however, noted that Whitaker only mentioned atherosclerosis once, in the context of "vascular conditioning." *LA Biomed* at 1065. According to the Federal Circuit:

> Upon observing that effect in the case of chronic treatment of patients with erectile dysfunction, Whitaker states that "[i]t is expected that vascular conditioning occurs after chronic administration of the PDE5 inhibitor, for example, after about three daily doses of up to 10 mg, preferably after five days of daily dosing, and more preferably after seven days of daily dosing." [Ex. 1086,] 13. Whitaker then states that "[i]t is theorized, but not relied upon herein that vascular conditioning is caused by a partial or complete reversal of circulatory dysfunctions in penile circulation arising from conditions such as diabetes, atherosclerosis, smoking, hypertension, or a combination of such factors," conditions that "result in thickening of the arterial wall, decreased arterial compliance, and decreased responsiveness to endogenous vasodilators, such as nitric oxide." *Id.*

Id. Importantly, the Federal Circuit notes that Whitaker's "vascular conditioning" theory is not supported by any evidence. *Id.* In addition, the Federal Circuit determined that we did not make any findings as to "the rate of incidence of atherosclerosis in males with erectile dysfunction," and, thus, "the presence of an underlying fibrotic condition could not be inferred." *Id.*

We acknowledge that Whitaker teaches the methods of treating male erectile dysfunction involving the chronic administration of a PDE5 inhibitor at a dose of 1 mg/day to 10 mg/day. Ex. 1086, 5[4]:13–18. We find, however that, as with Montorsi, Whitaker did not treat only patients with underlying fibrosis, did not identify those patients with underlying fibrosis, and did not report any effect that sildenafil may have had on fibrosis. For instance, Example 6 of Whitaker, which we relied upon in our Final Written Decision (FWD 17, 26–27), administered the PDE 5 inhibitor to patients suffering from erectile dysfunction, that is, patients that have a "persistent inability to attain and/or maintain an erection adequate to permit satisfactory sexual performance" (Ex. 1086, 35:19–24). In order to determine efficacy, Whitaker looked at the ability to maintain an erection and other parameters of sexual performance. Ex. 1086, 36:8–27. Thus, Whitaker does not specifically teach or suggest administering the PDE 5 inhibitor sildenafil to men who have underlying penile tunical fibrosis and corporal tissue fibrosis.

Petitioner contends further that although Montorsi may not be limited to patients with underlying penile fibrosis, all that is required is "that the fibrotic patient population is obvious to treat." Op. Br. 4 (citing *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Trust*, 764 F.3d

[4] Like Petitioner, we rely on the page numbers added by Petitioner to this Exhibit. Thus, page 5 is page 5 of 53.

1366, 1380–81 (Fed. Cir. 2014) (holding that the ordinary artisan would have easily envisaged the claimed subset of rheumatoid arthritis patients); *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1098–99 (Fed. Cir. 2015) (holding that it would have been obvious to treat women suffering from irritable bowel syndrome based on prior art disclosing that a majority of irritable bowel syndrome patients were women who would respond to the drug claimed). That is, Petitioner asserts, because the ordinary artisan "would have envisaged the fibrotic subpopulation, treating the fibrotic patient population is obvious." Reply Br. 1 (citing Ex. 1089 ¶¶ 60–69; Ex. 1121 ¶¶ 102–106, 124–134).

Because Montorsi concentrates on patients with erectile dysfunction associated caused by CVOD, Petitioner avers that it would have been obvious to the ordinary artisan to treat patients with fibrosis with a PDE 5 inhibitor. Op. Br. 4 (citing Ex. 1089 ¶ 60; Ex. 1121 ¶¶ 124–134). Whitaker, Petitioner argues, also provides a reason to treat fibrotic patients as "[i]t describes a target population that would benefit from PDE5 inhibitor treatment as ED patients with 'circulatory dysfunctions in penile circulation arising from conditions such as diabetes, atherosclerosis, smoking, hypertension, or a combination of such factors.'" *Id.* at 4–5 (citing Ex. 1086, 14). Petitioner asserts that those vascular risk factors "cause chronic hypoxia . . . that result in CVOD." *Id.* at 5 (citing Ex. 1051, 31; Ex. 1089 ¶¶ 46, 61–65; Ex. 1033, 274; Ex. 1086, 14; Ex. 1051, 31; Ex. 1047, 5; Ex. 1058, 1328; Ex. 1085, S18; Paper 44, 19; Pet. 21 n.17). Petitioner maintains that the ordinary artisan would have treated fibrotic patients with a PDE 5 inhibitor "based on the understanding that Whitaker's penile circulatory dysfunction patients have the cavernosal fibrosis that 'always

develops' to worsen penile circulatory dysfunction in ED patients." *Id.* (citing Ex. 1121 ¶¶ 103–110; Ex. 1107, 83; Ex. 1047, 5; Ex. 1001, 48:34–44; Paper 25, 17). Thus, Petitioner contends, even though not all of Whitaker's target patients may have penile fibrosis, it would have been obvious to treat penile fibrosis as it "is a 'common denominator'" among erectile dysfunction patients with the vascular risk factors identified by Whitaker. *Id.* (citing Ex. 1001, 48:44–54; Ex. 1089 ¶ 63; Ex. 1121 ¶ 110).

Petitioner asserts further that the prior art as a whole "established the link between penile corporal tissue fibrosis and the patients of Montorsi and Whitaker." *Id.* at 6 (citing Ex. 1089 ¶¶ 61-71; Ex. 1121 ¶¶ 148-155; Ex. 1047, 5; Ex. 1106, 168). Moreover, Petitioner contends, Patent Owner admits "that fibrosis is a common denominator underlying certain ED, as it (1) 'gradually develops in aging, diabetes, and other risk factors for erectile dysfunction' and (2) 'is the only real pathological link between some sexual dysfunctions and some other conditions within aging and diabetes related arterial disease, such as arteriosclerosis, arterial stiffness, and systolic hypertension.'" *Id.* (citing Ex. 1007 ¶ 23; Ex. 1008, 3-6; Ex. 1009, 7-9; Ex. 1089 ¶ 84; Ex. 1121 ¶ 62).

Patent Owner responds that Petitioner "contends for the first time that Montorsi and Whitaker nevertheless make it 'obvious to treat 'individuals with penile fibrosis by administering PDE-5 inhibitors on a continuous long-term basis." Res. Br. 4 (citing Op. Br. 4–5). According to Patent Owner, that argument asks us to find that fibrosis is inherently present in Montorsi's and Whitaker's patients. *Id.* An inherent limitation, Patent Owner asserts, "necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art" (citing *PAR Pharm., Inc. v.*

TWI Pharm., Inc., 773 F.3d 1186, 1195–96 (Fed. Cir. 2014)), contending that "[i]t is *undisputed* that erectile dysfunction—even in atherosclerotic or aging patients—is not necessarily caused by penile fibrosis." Res. Br. 4 (citing Ex. 2023 ¶¶ 21–28, 148; Ex. 2103, 42:8–11, 112:8–11; Ex. 2066, 19).

Patent Owner asserts that the *Abbvie* and *Prometheus* cases, relied upon by Petitioner, are distinguishable. Res. Br. 4. In those cases, Patent Owner contends, "the patentee tried to extend the patent term for a method of treatment by obtaining subsequent claims to a narrower target population—i.e., by claiming a species within the originally claimed genus—despite the absence of unexpected results or change in treatment method." *Id.* at 4–5 (citing *Abbvie*, 764 F.3d at 1378–81; *Prometheus*, 805 F.3d at 1097–1101). Here, Patent Owner argues, penile fibrosis is not necessarily a species of erectile dysfunction because, and as found by the Federal Circuit, penile fibrosis does not necessarily result in erectile dysfunction, and erectile dysfunction can have causes other than penile fibrosis. *Id.* at 5 (citing *LA Biomed.*, 849 F.3d at 1059).

As to the "link between penile corporal tissue fibrosis and the patients of Montorsi and Whitaker," Patent Owner responds "the Federal Circuit found that Montorsi's suggestions for 'further study' were not specific to patients with penile fibrosis, and rejected Lilly's contention that Whitaker's 'vascular conditioning' discloses a link to penile fibrosis." Res. Br. 5–6 (quoting Op. Br. 6; citing *LA Biomed.*, 849 F.3d at 1065–66). Moreover, Patent Owner asserts, Petitioner's "assertion that the Federal Circuit did not reverse the Board's finding that 'Montorsi and Whitaker suggest treating patients with ED associated with atherosclerosis with a PDE5 inhibitor,' . . . is incorrect," as the "Court stated that substantial evidence does not support

the Board's finding as to either reference." *Id.* at 6 (quoting Op. Br. 7; citing *LA Biomed*, 849 F.3d at 1065).

In its Reply Brief on Remand, Petitioner counters that the references teach erectile dysfunction caused by CVOD, and not erectile dysfunction generally. Reply Br. 1 (citing Ex. 1089 ¶ 60; Ex. 1121 ¶¶ 124–134). According to Petitioner, because the ordinary artisan "would have envisaged the fibrotic subpopulation, treating the fibrotic patient population is obvious." *Id.* (citing Ex. 1089 ¶¶ 60–69; Ex. 1121 ¶¶ 102–106, 124–134; Paper 44, 14, 22). Thus, Petitioner asserts, the ordinary artisan would have treated

> the fibrotic patients of Montorsi and Whitaker with daily, long-term PDE5 inhibitor administration based on their express suggestions for daily treatment (Ex. 1051, 31; Ex. 1086, ¶16), their overlapping patient populations (Ex. 1089, ¶¶ 42-53; Ex. 1121, ¶¶ 148-54), their suggested treatment benefits, such as increased NPT and improved vascular conditioning (Ex. 1051, 31; Ex. 1086, 1, 6, 13-14, 39 of 53), and Porst's disclosure that daily administration is safe (Ex. 1096, S76). *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007) (motivation may be based on interrelated prior art teachings).

Id. at 2–3.

We conclude that Petitioner has not established by a preponderance of the evidence that the ordinary artisan would have understood that it would have been obvious to treat patients having penile tunical fibrosis and corporal tissue fibrosis with a PDE5 inhibitor in view of the teachings of Montorsi, Whitaker, and Porst. As discussed above, Petitioner only relies on Porst for its teaching that daily administration of a PDE5 inhibitor is safe, and, thus, we do not discuss it further in this context.

As to Montorsi, we acknowledge that Montorsi teaches that "it seems reasonable to hypothesize that the ED from aging is the result of atherosclerosis-induced cavernosal ischaemia leading to cavernosal fibrosis and veno-occlusive dysfunction." Ex. 1051, 31. We note further that Montorsi teaches that "administering 100 mg of sildenafil at bedtime in patients with ED of various aeteologies produces a statistically significant increase in the nocturnal penile rigidity and tumescence activity." *Id.* Thus, Montorsi teaches this has "opened the door to further study investigating the possible dosage of sildenafil to be administered daily at bedtime to prevent or treat ED in the elderly patient." *Id.*

As noted by the Federal Circuit in *LA Biomed*, however, the study in Montorsi is not limited to aging males with atherosclerosis, or even patients with atherosclerosis. *LA Biomed* at 1065. In addition, Petitioner does not point us to any evidence as to the rate or incidence of atherosclerosis in males with erectile dysfunction. *Id.*

That is, Montorsi administered the PDE5 inhibitor sildenafil to 411 elderly patients suffering from erectile dysfunction with a broad-spectrum of etiologies and 71 elderly patients with erectile dysfunction and diabetes. Ex. 1051, 32. Montorsi looked at erectile and sexual function to demonstrate the efficacy of the administration of sildenafil. *Id.* at 33. Specifically, Montorsi reported that "[m]ore than two-thirds of the men in the broad spectrum ED subgroup and one-half of the men in the ED and diabetes subgroup reported improved erections with sildenafil treatment." *Id.*

Based on that disclosure, the ordinary artisan, at best, may have recognized that male atherosclerotic patients with erectile dysfunction may be treated with sildenafil to treat the *erectile dysfunction*. As noted by the

Federal Circuit, however, "erectile dysfunction can have causes other than penile fibrosis, and . . . penile fibrosis does not necessarily result in erectile dysfunction." *LA Biomed*, 849 F.3d at 1059. Thus, although Montorsi teaches treating a patient group that may include patients with fibrosis such as patients suffering from atherosclerosis, Montorsi does not direct the ordinary artisan to treat a patient group suffering from penile tunical fibrosis and corporal tissue fibrosis, which would include those without associated erectile dysfunction, with sildenafil. Stated differently, just because Montorsi teaches that there may be an association between CVOD and erectile dysfunction, and that a PDE5 inhibitor, such as sildenafil, may be used to treat erectile dysfunction, that does not mean that the ordinary artisan would understand that a PDE5 inhibitor would be effective in treating underlying penile tunical fibrosis or corporal tissue fibrosis. Montorsi, therefore, does not render obvious treating patients with penile tunical fibrosis or corporal tissue fibrosis with a PDE5 inhibitor.

Again, Whitaker does not remedy that deficiency. We recognize that Whitaker teaches chronic daily administration of a PDE5 inhibitor for as long as the erectile dysfunction may last. We further recognize that Whitaker also teaches that PDE5 inhibitors may have a "vascular conditioning" effect with chronic administration, and that the "vascular conditioning is caused by a partial or complete reversal of circulatory dysfunctions in penile circulation arising from conditions such as diabetes, atherosclerosis, smoking, hypertension, or a combination of such factors." Ex. 1086, 13–14. But, as noted by the Federal Circuit and already discussed above, Whitaker does not provide any evidence to support that theory. *See LA Biomed* at 1065. And, yet again, similarly to Montorsi, Whitaker's

examples are not limited to a patient population with underlying fibrosis, but are only described as patients with erectile dysfunction. Ex. 1086, 35, 38. Thus, for the reasons set forth above with respect to Montorsi, Whitaker, either alone or in combination with Montorsi, does not render obvious treating patients with penile tunical fibrosis or corporal tissue fibrosis.

Petitioner's argument that the prior art as a whole "established the link between penile corporal tissue fibrosis and the patients of Montorsi and Whitaker" (Op. Br. 6) is not persuasive in view of the Federal Circuit's decision in *LA Biomed*. In our Final Written Decision, we recognized "Petitioner cites multiple references as evidence that the ordinary artisan would have understood that conditions such as diabetes, atherosclerosis, smoking, and hypertension lead to penile fibrosis, and in particular CVOD. Pet. 21, *see also id.* n.17 (quoting from multiple cited references that purportedly establish a link between the above conditions and CVOD)." FWD 19. The Federal Circuit, however, even in view of that acknowledgment, concluded that our findings were "insufficient to establish obviousness under the correct constructions of 'an individual with at least one of a penile tunical fibrosis and corporal tissue fibrosis' . . . ." *LA Biomed* at 1064.

Petitioner's reliance on *Abbvie* and *Prometheus* is also unavailing. That is, we agree with Patent Owner that those cases are distinguishable because in those cases "the patentee tried to extend the patent term for a method of treatment by obtaining subsequent claims to a narrower target population—i.e., by claiming a species within the originally claimed genus—despite the absence of unexpected results or change in treatment method" (Res. Br. 4–5). Thus, in *Abbvie*, the claims at the patent at issue

were a species of the genus of the invalidating patent. *Abbvie*, 764 F.3d 1366. Specifically, the claims of the patent at issue deemed to be obvious over the invalidating patent were drawn to treating a more acute form of the disease being treated by the invalidating patent. *Id.* at 1378. In *Prometheus*, again, the claims of the patent at issue were a species of the genus claimed by the invalidating patent. *Prometheus*, 805 F.3d at 1098. Although acknowledging that a species may be patentable over a genus (*id.*), the Federal Circuit concluded that the ordinary artisan would have found it obvious to treat the subset of patients recited by the claims of the patent at issue (*id.* at 1100–01).

Here, we find that the claims at issue do not treat a subset of patients that the ordinary artisan would have envisaged from the patient populations of Montorsi and Whitaker. In that regard, we initially find that as the Federal Circuit stated, patients with erectile dysfunction do not necessarily have underlying fibrosis, and patients suffering from penile tunical fibrosis or corporal tissue fibrosis do not necessarily have erectile dysfunction. *See* LA *Biomed* at 1053, 1059.

Moreover, as we have already stated, although Montorsi hypothesizes that erectile dysfunction in the aging male may be the result of CVOD (Ex. 1051, 31), Montorsi did not limit its study to patients with underlying CVOD, but studied aging males (greater than 65 years in age) with erectile dysfunction of various etiologies (*id.* at 32). In addition, Montorsi did not look at the effect of the PDE5 inhibitor on CVOD or fibrosis generally, but looked at its effect on erectile dysfunction and sexual satisfaction generally. *Id.* at 33. Whitaker also did not limit its patient population to patients with underlying CVOD, or even patients with the risk factors of diabetes,

atherosclerosis, smoking, hypertension, or a combination of such factors. Ex. 1086, 14. Rather, Whitaker described its population as men with erectile dysfunction. *Id.* at 35, 37. Again, the efficacy results looked at by Whitaker were effect on erectile dysfunction and other sexual parameters. *Id.* at 36, 38–39. What is missing from both Whitaker and Montorsi is a teaching or suggestion that the ordinary artisan would understand that an improvement in erectile dysfunction or sexual function correlates to an improvement in penile tunical fibrosis or corporal tissue fibrosis. That is especially true given that neither Montorsi nor Whitaker limits its patient population to those with recognized underlying fibrosis. In particular, as the sildenafil appeared to treat the erectile dysfunction in patients regardless of the underlying cause, the ordinary artisan would not necessarily understand that the sildenafil was also treating underlying penile tunical fibrosis and corporal tissue fibrosis.

We have also considered Petitioner's argument that the ordinary artisan at the time of invention would have had a reasonable expectation of arresting or regressing fibrosis. Op. Br. 7–14. But as we have found that Petitioner has not established by a preponderance of the evidence that the art teaches or suggests administering a PDE 5 inhibitor to an individual with at least one of a penile tunical fibrosis and corporal tissue fibrosis as construed above, Petitioner also does not establish that the ordinary artisan would have had a reasonable expectation of arresting or regressing one or both of those conditions.

In that regard, as discussed above, although both Montorsi and Whitaker teach that the PDE5 inhibitor, sildenafil, was efficacious in treating erectile dysfunction, the patient group treated was suffering from

erectile dysfunction caused by various etiologies, and not just underlying fibrotic conditions. Thus, Montorsi and Whitaker do not provide an adequate evidentiary basis for finding that a skilled artisan had a reasonable expectation of success of arresting or regressing any penile tunical fibrosis and corporal tissue fibrosis because they do not look at the effects of the PDE5 on anything besides erectile dysfunction and general sexual function. Stated differently, given that neither Montorsi nor Whitaker limits its patient population to those with recognized underlying fibrosis, we are unable to determine on this record that the ordinary artisan would reasonably expect that the sildenafil was arresting or regressing the underlying penile tunical fibrosis and corporal tissue fibrosis.

F. Conclusion

We conclude, taking into the account the decision of the Court of Appeals for the Federal Circuit in *LA Biomed*, that Petitioner has failed to demonstrate the unpatentability of challenged claims 1–5 by a preponderance of the evidence.

ORDER

Accordingly, it is

ORDERED that Petitioner has failed to demonstrate the unpatentability of claims 1–5 by a preponderance of the evidence; and

FURTHER ORDERED that this is a final written decision of the Board under 35 U.S.C. § 318(a). Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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