

United States Court of Appeals for the Federal Circuit

IN RE: ETHICON, INC.,
A JOHNSON & JOHNSON COMPANY,
Appellant

2015-1696

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 95/000,542, 95/000,552.

Decided: January 3, 2017

JOSEPH LUCCI, Baker & Hostetler LLP, Philadelphia, PA, argued for appellant. Also represented by JOHN FRANK MURPHY, CHARLIE C. LYU.

FARHEENA YASMEEN RASHEED, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor Michelle K. Lee. Also represented by THOMAS W. KRAUSE, SCOTT WEIDENFELLER.

Before NEWMAN, LOURIE, and DYK, *Circuit Judges*.
Opinion for the court filed by *Circuit Judge LOURIE*.
Dissenting opinion filed by *Circuit Judge NEWMAN*.
LOURIE, *Circuit Judge*.

Ethicon, Inc. (“Ethicon”) appeals from the U.S. Patent and Trademark Office (“PTO”) Patent Trial and Appeal Board’s (“the Board’s”) decision in a merged *inter partes* reexamination affirming the examiner’s obviousness rejection of claims 1–17 and 19–23 of U.S. Patent 7,591,844 (“the ’844 patent”). *See Boston Sci. SCIMED v. Cordis Corp.*, No. 2014-008135, 2015 WL 883933 (P.T.A.B. Feb. 27, 2015) (“Decision”). Because the Board did not err in its obviousness conclusion, we affirm.

BACKGROUND

Ethicon owns¹ the ’844 patent, which relates to intraluminal medical devices for the local delivery of drugs, *e.g.*, drug-eluting stents, and methods for maintaining drugs on those devices. ’844 patent col. 1 ll. 21–31, col. 5 ll. 50–57. Angioplasty can be used to alleviate blockages of blood vessels. *Id.* col. 1 ll. 33–46. However, expansion of the balloon catheter during angioplasty can result in injury to the smooth muscle cells within the vessel wall, which can lead to restenosis, the gradual re-closure of the vessel. *Id.* col. 1 l. 46–col. 2 l. 45. The ’844 patent teaches that stent coatings themselves, and stent coatings delivering drugs locally, may be capable of reducing restenosis. *Id.* col. 4 ll. 43–54. The ’844 patent teaches that previously “[s]tents with coatings made from polyvinylidene fluoride [VDF] homopolymers and containing pharmaceutical/therapeutic agents or drugs for release have been suggested.” *Id.* col. 5 ll. 4–6.

Claim 1 is representative of the challenged claims and reads as follows:

¹ During the pendency of this appeal, Cordis Corporation assigned the ’844 patent to Ethicon. For simplicity, we refer to the owner of the ’844 patent throughout as Ethicon.

1. A device for intraluminal implantation in a vessel comprising a balloon-expandable stent and a pharmaceutical agent-containing coating, said coating comprising a biocompatible polyfluoro copolymer that comprises about eighty-five weight percent vinylidenefluoride [VDF] copolymerized with about fifteen weight percent hexafluoropropylene [HFP] and at least one pharmaceutical agent intermixed with said copolymer, wherein said coating has not been subjected to a maximum temperature greater than 60° C. [sic] during the coating process or afterward, thereby providing an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent.

'844 patent col. 37 l. 59–col. 38 l. 3.

Ethicon sued Boston Scientific SCIMED (“Boston Scientific”) and Abbott Laboratories (“Abbott” and, collectively with Boston Scientific, “Requesters”) in the United States District Court for the District of New Jersey on allegations of, *inter alia*, infringement of the '844 patent. Subsequently, in 2010, the Requesters each filed separate requests for *inter partes* reexamination of the '844 patent. The PTO merged and granted the requests for *inter partes* reexamination.

During the reexamination, Ethicon cancelled claims 18 and 24 by amendment. The examiner rejected remaining claims 1–17 and 19–23 as obvious over, *inter alia*, U.S. Patent 5,824,048 (“Tuch”), U.S. Patent 4,816,339 (“Tu”), and U.S. Patent 3,178,399 (“Lo”), and relied on a translation of Fr. Patent 2,785,812 (“Le Morel”) to reject certain dependent claims. The examiner found that the evidence submitted by Ethicon regarding objective indicia of nonobviousness was insufficient to outweigh the conclusion of obviousness. Ethicon appealed to the Board,

arguing that the examiner erred in combining the prior art references and by discounting the objective indicia.

Tuch discloses intravascular stents, including balloon-expandable stents, with a coating on the tissue-contacting surface that includes a polymer and a drug. Tuch col. 2 ll. 35–42, col. 4 ll. 10–13. Tu discloses implantable medical devices such as vascular grafts and heart valve leaflets made from a multi-layered polytetrafluoroethylene/elastomer material. Tu col. 1 ll. 21–32. Tu lists VDF:HFP copolymer first in its list of potential elastomers, *id.* col. 4 ll. 30–32, and states that the elastomer may contain drugs, *e.g.*, heparin, for release into the surrounding environment, *id.* col. 9 ll. 65–68. Lo discloses properties of VDF:HFP copolymer at various weight ratios, including 85:15. Lo Fig. 1, col. 9 ll. 15–36. Le Morel discloses stents with a VDF:HFP coating. J.A. 10748–49.

The Board affirmed the examiner's rejection of claims 1–17 and 19–23 as obvious. The Board began its analysis with Tuch and found that Tuch teaches that the polymer in the coating may be either biostable or bioabsorbable and lists VDF as an example of a suitable biostable polymer. *Decision*, at *4. The Board also found that Tuch teaches that its list of polymers, which includes “vinyl halide polymers and copolymers,” is not exhaustive and that Tuch's teachings would not have limited a skilled artisan to the explicitly listed polymers or dissuaded a skilled artisan from selecting a VDF copolymer. *Id.* at *7.

The Board additionally found that Tuch discloses “a problem with coatings with low elasticity,” *id.* at *10, and that biocompatibility and elasticity are “useful” characteristics for the polymer in its stent coatings, *id.* at *9. See also *id.* at *4–5. The Board found that “[s]ince Tuch teaches a problem with cracking when materials having little elasticity are utilized in the polymer layer, one of ordinary skill in the art would have reasonably sought

materials with high elasticity to avoid the problem when the stent is expanded.” *Id.* at *9.

The Board then analyzed Tu and Lo in light of Tuch’s teachings. Tu states that “[i]t is not desired to have the elastomer permeate the poly(tetrafluoroethylene)/elastomer layer and migrate into the lumen.” Tu col. 8 ll. 40–43. The Board found that this statement only relates to a particular embodiment and that Tu also teaches that the poly(tetrafluoroethylene)/elastomer layer can be used in medical devices such as heart valve leaflets where the VDF:HFP elastomer would be in contact with blood. *Decision*, at *5, *8. The Board additionally found that Tu teaches that VDF:HFP copolymer possesses the useful properties of biocompatibility and elasticity taught by Tuch and that it is also useful for coatings containing a therapeutic substance. *Id.* at *5, *9–10.

The Board similarly found that Lo teaches that 85:15 VDF:HFP “is advantageous with respect to flexibility, elasticity, extensibility, tensile strength, and reverse elongation.” *Id.* at *10. The Board found that a skilled artisan would have been motivated to use 85:15 VDF:HFP, possessing these advantageous properties, as the polymer in Tuch’s stent because “Tuch teaches a problem with coatings with low elasticity.” *Id.* The Board also found that “the skilled worker would have reasonably consulted Lo to determine the optimal concentrations for each component, even if Lo does not teach the use of VDF:HFP for medical implants.” *Id.*

The Board also considered Ethicon’s evidence regarding objective indicia of nonobviousness but found that none of it was entitled to substantial weight. Ethicon alleged copying by the Requesters and pointed to the alleged commercial success of, unexpected results obtained by, and industry praise for certain stents sold by the Requesters to support its argument that the claims would not have been obvious.

The Board found that Ethicon did not submit factual evidence or analysis to support its copying allegations and thus gave them “little weight.” *Decision*, at *11. The Board similarly found that the evidence submitted did not establish that the alleged commercial success, industry praise, or unexpected results were due to the claimed 85:15 VDF:HFP coating rather than to an unclaimed feature such as the drug or stent design. *Id.* at *11–14. Regarding unexpected results, the Board also found that Ethicon did not establish that the comparisons relied on were to the closest prior art or provide an expert opinion that the results pointed to would have been unexpected. *Id.* at *13–14.

The Board also concluded that under *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), “even if Tuch did not disclose a problem with its polymers, one of ordinary skill in the art would have found it obvious to have employed the known polymers of Tu and Lo for their known and expected properties” and that “the reason to combine [the references] could be provided by the ‘normal desire of scientists or artisans to improve upon what is already generally known.’” *Decision*, at *6 (quoting *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003)).

Ethicon timely appealed, and the Director of the PTO (the “Director”) intervened pursuant to 35 U.S.C. § 143, filing a brief and participating in oral argument. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Our review of a Board decision is limited. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). We review the Board’s legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), but we review the Board’s factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might

accept the evidence to support the finding. *Consol. Edison Co. of New York v. NLRB*, 305 U.S. 197, 229 (1938).

Obviousness is a question of law, based on underlying factual findings, including what a reference teaches, whether a person of ordinary skill in the art would have been motivated to combine the references, and any relevant objective indicia of nonobviousness. *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1047–48, 1051 (Fed. Cir. 2016) (en banc).

The Supreme Court has cautioned that the obviousness inquiry must “guard against slipping into use of hindsight and . . . resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966) (internal citations and quotations omitted). The Court has also instructed that “when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result.” *KSR*, 550 U.S. at 416. Similarly, § 103 likely bars patentability unless “the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417.

Generally, a skilled artisan would only have been motivated to combine analogous art. Prior art is analogous where either (1) “the art is from the same field of endeavor, regardless of the problem addressed” or (2) even if the reference is not within the same field of endeavor, “the reference still is reasonably pertinent to the particular problem with which the inventor is involved.” *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992) (citation omitted). Whether a reference is analogous art is a question of fact. *Id.* at 658.

Ethicon argues that the Board’s obviousness rejection impermissibly relies on hindsight and fails to provide any reason why one of ordinary skill in the art would have

combined the prior art references to create the claimed invention. Specifically, Ethicon argues that Tuch provides no motivation to select polymers other than those it describes and that neither Tuch nor Tu provide a motivation to select VDF or VDF:HFP as the polymer coating. Additionally, Ethicon faults the Board for not making certain fact findings relating to the motivation to combine references.

The Director responds that substantial evidence supports the Board's factual findings, and the Board's obviousness conclusion was proper under *KSR*. The Director contends that the claimed invention is merely the simple substitution of a coating (VDF:HFP) known to be useful in *in vivo* applications, including stents, in a weight ratio (85:15) known to provide a good balance between strength and elasticity, for the VDF coating disclosed in Tuch. The Director contends that Ethicon's arguments are contrary to the teachings of the references and not supported by applicable law.

We agree with the Director that substantial evidence supports the Board's factual findings. *KSR* directs that an explicit teaching, suggestion, or motivation in the references is not necessary to support a conclusion of obviousness. 550 U.S. at 415–16. The Supreme Court has instructed that “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions,” *id.* at 417, and apply “an expansive and flexible approach” to obviousness, *id.* at 415.

Here, the Board made sufficient factual findings under the circumstances to support its obviousness conclusion and those findings are supported by substantial evidence. Tuch teaches that the polymer must be “biocompatible.” Tuch col. 5 ll. 14–16. Tuch explains that coating overlayers “made with materials which have little elasticity . . . can sustain significant cracking during

[stent] deformation” and that such cracking can result in more rapid elution of drugs. *Id.* col. 7 ll. 11–15. Tuch teaches that “inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent in a resilient[, *i.e.*, elastic,] matrix during expansion of the stent and also slows the administration of drug following implantation.” *Id.* col. 2 ll. 42–46. Those teachings constitute substantial evidence supporting the Board’s findings that Tuch teaches that elasticity and biocompatibility are useful polymer characteristics and that coatings with low elasticity are problematic.

The Board relied on Tu and Lo for teachings regarding an 85:15 weight ratio of VDF:HFP. Tu teaches that the elastomer “promotes the elasticity [and] strength” of the medical devices, Tu col. 3 ll. 61–64, and lists VDF:HFP first in its list of preferred elastomers, *id.* at col. 4 ll. 30–32. Lo similarly teaches VDF:HFP copolymers with “varying degrees of flexibility, elasticity and extensibility,” Lo col. 2 ll. 33–48, and that a weight ratio of 85:15 VDF:HFP achieves the optimal combination of tensile strength and reversible elongation, *id.* Fig. 1, col 9 ll. 15–36. These teachings of all of the required components of the claims support the Board’s combination of the three references to address the problem regarding elasticity taught by Tuch.

Ethicon also challenges certain factual findings made by the Board regarding the references. First, Ethicon contends that Tuch never suggests that the elasticity of the polymer itself is an important characteristic and asserts that it teaches away from using non-bioabsorbable coatings such as VDF:HFP by recommending bioabsorbable polymers. Second, Ethicon asserts that Tu is directed to medical devices other than stents and teaches away from allowing an elastomeric polymer such as VDF:HFP to be in contact with blood. Third, Ethicon argues that Lo is decades old, nonanalogous art that provides no motivation to combine its teachings with

medical devices. Ethicon asserts that Lo is directed to coatings for harsh, industrial applications, not implantable medical devices.

The Director responds that the challenged factual findings are supported by substantial evidence. First, the Director contends that Ethicon's arguments are contrary to the teachings of Tuch. Second, the Director asserts that Ethicon ignores the similar properties shared by coatings suitable for the devices disclosed by Tu and the '844 patent and ignores embodiments in Tu that teach that the blood contacting layer can comprise VDF:HFP. Third, the Director contends that Ethicon ignores that Lo discloses properties of VDF:HFP that would have been relevant to a skilled artisan considering a coating on a stent and that Lo's age is irrelevant absent a showing of long-felt need or the failure of others.

We agree with the Director that substantial evidence supports the challenged findings. First, as discussed above, substantial evidence supports the Board's findings that Tuch teaches that elasticity is a useful polymer characteristic and that coatings with low elasticity are problematic. Additionally, Tuch teaches that its "polymer may be *either* a biostable or bioabsorbable polymer," Tuch col. 5 ll. 16–17 (emphasis added), and lists VDF as an example of a suitable biostable polymer, *id.* col. 5 ll. 33–53. Although Tuch states that a "bioabsorbable polymer is probably more desirable," *id.* col. 5 ll. 19, this statement, absent clear discouragement from use, does not compel a finding that Tuch teaches away from using VDF:HFP as a stent coating. *See Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 977 (Fed. Cir. 2014) ("Yet simply because the curved blade configurations are not preferred embodiments does not result in the Davison patent teaching away from use of a curved blade, 'absent clear discouragement of that combination.'" (quoting *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1356 (Fed.Cir.2012))); *see also In re Applied Materi-*

als, Inc., 692 F.3d 1289, 1298 (Fed. Cir. 2012) (“A reference must be considered for everything that it teaches, not simply the described invention or a preferred embodiment.”).

Second, although Tu states that “[i]t is not desired to have the elastomer permeate the poly(tetrafluoroethylene)/elastomer layer and migrate into the lumen,” Tu col. 8 ll. 40–43, substantial evidence supports the Board’s finding limiting this statement to a particular embodiment and its finding that Tu teaches that the elastomer can be in contact with blood. Tu teaches that its invention has a “very broad application in biomedical devices, such as . . . heart valve leaflets,” *id.* col. 2 ll. 36–40, and an alternative embodiment where the “combination of layers provides for better hydrophilicity due to the elastomer in the luminal layer,” *id.* col. 9 ll. 56–60. *See also id.* col. 1 ll. 27–32, col. 9 ll. 65–68.

Third, we can discern no error in the Board’s reliance on Lo. The ’844 patent states that “[i]t would be advantageous to develop coatings for implantable medical devices . . . that possess physical and mechanical properties effective for use in such devices” ’844 patent col. 5 ll. 11–18. The Board relied on Lo for “teaching the properties of VDF:HFP” at different ratios of copolymer. *Decision*, at *10. Substantial evidence supports finding that Lo’s teachings are at least “reasonably pertinent to the particular problem with which the inventor is involved,” *In re Clay*, 966 F.2d at 659, and that a skilled artisan would have combined those teachings with Tuch and Tu. The normal desire of artisans to improve upon what is already generally known can provide the motivation to optimize variables such as the percentage of a known polymer for use in a known device. *See In re Peterson*, 315 F.3d at 1330; *see also KSR*, 550 U.S. at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”).

Furthermore, the age of Lo does not undermine the Board's reliance on it for teaching the ratio of the copolymer components. "The mere age of the references is not persuasive of the unobviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem." *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977) (citation omitted). Ethicon presented no evidence of a long-felt need or the failure of others.

Finally, Ethicon argues that the Board erred by discounting its proffered objective indicia of nonobviousness. Ethicon asserts that copying, commercial success, industry praise, and unexpected results support the nonobviousness of the '844 patent.

The Director responds that Ethicon's evidence regarding objective indicia is insufficient to overcome the *prima facie* case of obviousness. The Director contends that Ethicon's arguments have scant support in the record and that the Board's factual findings are supported by substantial evidence.

We agree with the Director that the Board properly weighed Ethicon's evidence of objective indicia. Ethicon relied solely on its expert's conclusory testimony to support its copying allegations. J.A. 3763. Regarding unexpected results, Ethicon's expert never even opined that the results pointed to would have been unexpected to a person of ordinary skill in the art. J.A. 3764. Moreover, the Board's finding that the evidence relied on by Ethicon to support its claims of commercial success, industry praise, and unexpected results did not establish that any success, praise or unexpected results were due to the 85:15 VDF:HFP coating, rather than to an unclaimed feature such as the drug or stent design, is supported by substantial evidence. *See* J.A. 3763–64; J.A. 4200–05. We can discern no reversible error in the Board's findings.

CONCLUSION

We have considered all of Ethicon's remaining arguments, but conclude that they are without merit. The Board's decision was supported by substantial evidence and was not erroneous as a matter of law. For the reasons set forth above, we affirm the Board's decision.

AFFIRMED

United States Court of Appeals for the Federal Circuit

IN RE: ETHICON, INC.,
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Appellant

2015-1696

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 95/000,542, 95/000,552.

NEWMAN, *Circuit Judge*, dissenting.

United States Patent No. 7,591,844 (“the ’844 Patent”) is for a balloon-expandable vascular stent having a drug-eluting coating of a copolymer of vinylidene fluoride and hexafluoropropylene in about 85/15 weight percent monomer ratio. Novelty is not disputed. On this *inter partes* reexamination requested by Boston Scientific Scimed and Abbott Laboratories, the PTAB held that the prior art rendered obvious the claimed vascular stent. I cannot agree, for no reference or combination of references, or common knowledge or common sense, teaches or suggests or motivates the claimed stent.

Claim 1 was accepted as representative:

1. A device for intraluminal implantation in a vessel comprising a balloon-expandable stent and a pharmaceutical agent-containing coating, said coating comprising a biocompatible polyfluoro co-

polymer that comprises about eighty-five weight percent vinylidene fluoride [VDF] copolymerized with about fifteen weight percent hexafluoropropylene [HFP] and at least one pharmaceutical agent intermixed with said copolymer, wherein said coating has not been subjected to a maximum temperature greater than 60° C during the coating process or afterward, thereby providing an adherent coating that remains adhered to the device upon expansion of the balloon-expandable stent.

'844 Patent, col. 37, l. 59–col. 38, l. 3. It was generally agreed that the novelty and advantages are due to the specific copolymer coating material for the balloon-expandable stent.

The references cited by the PTO Board recite thousands of polymer and copolymer components for stent coating materials, but not the copolymer of the '844 Patent, although this copolymer was known for other uses. There is no hint, no suggestion, of its use as a drug-eluting coating in a vascular stent, nor were its advantages foreseen. Nonetheless the Board deemed it obvious,¹ and this court agrees. I respectfully dissent.

Errors of fact, analysis, and law

The Board relied on three groups of references, and the court has followed this pattern on appellate review. The Board's first set of references was cited to show that

¹ *Boston Scientific Scimed v. Cordis Corp.*, No. 2014-008135, 2015 WL 883933 (P.T.A.B. Feb. 27, 2015) (“Board Op.”). The successful requesters withdrew from this appeal, and the PTO Director has intervened to defend the Board’s decision, with the filing of briefs and participation in oral argument.

polymer-coated vascular stents were known; the second set was “consulted” to show various polymers used in medical devices and structures unrelated to vascular stents; and the third set was cited to show that the '844 Patent's copolymer was known for unrelated uses such as clothing, boots, helmets, electrical tapes, and linings for tanks and storage vessels. No reference or combination of references teaches or suggests or motivates or otherwise renders obvious the '844 Patent's vascular stent.

The coated vascular stent references (Tuch)

The Board provided a foundation for its analysis with the first set of references, focusing on the Tuch patent, which shows polymer-coated drug-eluting vascular stents. Such vascular stents were known, and the '844 Patent so states. U.S. Patent No. 5,824,048 (the Tuch reference) names hundreds of monomers encompassing thousands of polymers and copolymers, and states that they may all be usable for vascular stents in various conditions. However, the specific '844 Patent's copolymer is not mentioned, and although the list includes one of the '844 Patent's comonomers, vinylidene fluoride, the other known monomer, hexafluoropropylene, is not mentioned. This silence cannot render obvious the omitted copolymer, for nothing in Tuch suggests selection of this omitted copolymer from the thousands of polymeric and other potential stent materials listed by Tuch:

The polymer may be either a biostable or a bioabsorbable polymer depending on the desired rate of release or the desired degree of polymer stability, but a bioabsorbable polymer is probably more desirable since, unlike a biostable polymer, it will not be present long after implantation to cause any adverse, chronic local response. Bioabsorbable polymers that could be used include poly(L-lactic acid), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxy-

butyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(imino-carbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid. Also, biostable polymers with a relatively low chronic tissue response such as polyurethanes, silicones, and polyesters could be used and other polymers could also be used if they can be dissolved and cured or polymerized on the stent such as polyolefins, polyisobutylene and ethylene-alphaolefin copolymers; acrylic polymers and copolymers, vinyl halide polymers and copolymers, such as polyvinyl chloride; polyvinyl ethers, such as polyvinyl methyl ether; polyvinylidene halides, such as polyvinylidene fluoride and polyvinylidene chloride; polyacrylonitrile, polyvinyl ketones; polyvinyl aromatics, such as polystyrene, polyvinyl esters, such as polyvinyl acetate; copolymers of vinyl monomers with each other and olefins, such as ethylene-methyl methacrylate copolymers, acrylonitrile-styrene copolymers, ABS resins, and ethylene-vinyl acetate copolymers; polyamides, such as Nylon 66 and polycaprolactam; alkyd resins; polycarbonates; polyoxymethylenes; polyimides; polyethers; epoxy resins; polyurethanes; rayon; rayon-triacetate; cellulose, cellulose acetate, cellulose butyrate; cellulose acetate butyrate; cellophane; cellulose nitrate; cellulose propionate; cellulose ethers; and carboxymethyl cellulose.

Tuch, col 5, ll. 16-53.

The Tuch encyclopedia cannot be taken to teach or suggest or motivate that the unmentioned copolymer of the '844 Patent should be identified and used in a vascular stent. “[T]he breadth of these choices and the numerous combinations indicate that these disclosures would not have rendered the claimed invention obvious to try.” *LeoPharma Prods., Ltd. v. Rea*, 726 F.3d 1346, 1356–57 (Fed. Cir. 2013). Nothing in the Tuch reference, or any other reference, suggests use of the '844 Patent's copolymer for vascular stents, even for experimentation:

[A]n invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art.

Bayer Schering Pharma AG v. Barr Labs., Inc., 575 F.3d 1341, 1347 (Fed. Cir. 2009).

However, the Board deemed it irrelevant that the '844 Patent's copolymer was omitted by Tuch, and erroneously found that this copolymer was “a prior art element used for its established function.” The Board stated:

It is unnecessary that Tuch disclose any shortcomings in its list of polymers for the ordinary skilled worker to have found it obvious to have employed an alternative polymer for its coating since it is obvious to use a prior art element for its established function.

Board Op. at 10–11. This finding has no support, for Tuch does not lead to the undisclosed copolymer of the '844 Patent or any established function in the drug-eluting vascular stents to which Tuch is directed. The “established function” of this copolymer is shown in the prior art to be quite different, as in the cited Lo reference, discussed *post*.

Tuch does not provide substantial evidence of the '844 Patent's copolymer as a stent material or possible stent

material. The “substantial evidence” standard of judicial review of Board findings “involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency’s decision.” *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). The Tuch reference as a whole, with its massive listing of thousands of polymers and copolymers but not the ’844 copolymer, does not provide substantial evidence of any suggestion or any reason to select the ’844 Patent’s copolymer for use in drug-eluting vascular stents.

“Consultation” of the Tu reference

Perhaps recognizing the inadequacy of Tuch, the Board “consulted” the Tu *et al.* reference, U.S. Patent No. 4,816,339. Tu describes multilayered “sutureable vascular implants” having “improved luminal hydrophobicity, compliance, strength and elasticity.” Tu, col. 2, ll. 7–11. The first Tu layer is made of poly(tetrafluoroethylene), the second layer is “a mixture of poly(tetrafluoroethylene) and elastomer,” and an optional third layer is made of “elastomer.” Tu, col. 3, ll. 48–65. Tu states that the elastomer may be selected from a diverse group of polymers and copolymers, including the ’844 Patent’s copolymer components:

The elastomer is preferably selected from the group consisting of polyvinylidene fluoride co-hexafluoropropylene, poly(tetrafluoroethylene-co-perfluoro(methylvinylether)), poly(tetrafluoroethylene-co-propylene), poly(vinylidene-co-chlorotrifluoroethylene), silicones, fluorosilicones, fluoroalkoxy phosphazenes, segmented copolyester ether, styrene butadiene block copolymers, polyethers[,] acrylonitrile butadienes, isoprenes, polyurethanes, and mixtures thereof.

Tu, col. 4, ll. 30–39. Tu’s preferred elastomers are a copolymer of tetrafluoroethylene and propylene, and

silicone. Tu, col. 4, ll. 61–66; col. 5, l. 7. The Board stated:

The reason to consult Tu is because Tuch's list of polymers is clearly not exhaustive in view of Tuch's description of broad classes of polymers, such as vinyl halide polymers and copolymers, and polyvinylidene halides. Tuch 6. Tuch also uses the transitional phrase "such as" in prefacing the list of biostable polymers and in reciting specific examples of the broader classes, indicating that Tuch did not confine the skilled worker to the explicit list, but contemplated polymers outside of it.

Board Op. at 7. Tu does not state that its multilayered suturable implants are useful in vascular stents, or suggest selection of any of its materials for this purpose. Tu cannot be read as teaching that its materials enlarge the listing of suitable stent polymers in Tuch, to place the Tu materials in the Tuch disclosure. The Tu devices are different products requiring different properties for different purposes.

The Board states that it consulted Tu "for teaching of a medical device comprising VDF:HFP." Board Op. at 3. Tu does not mention vascular stents, and suggests no composition or properties for such use. It is apparent that the Tu multilayered structure differs from a vascular stent, and the Board did not find otherwise. Also, as an additional difference Tu requires "curing" at a temperature of about 150° C to about 350° C, Tu, col. 7, ll. 66–68; col. 9, ll. 12–14, excluding the '844 Patent product's temperature ceiling of "60° C during the coating process or afterward." '844 Patent, col. 37, l. 66–col. 38, l. 1.

The Board states that Tu shows that the VDF:HFP copolymer "has the properties described in Tuch as useful for its stent coating." Board Op. at 14. The Tuch properties are not the properties of Tu's multilayered suturable

vascular implants. Tu states that its implants have elasticity “because of the arrangement of layers”:

The biologically compatible material of the present invention has excellent compliance, strength and elasticity because of the arrangement of layers of poly(tetrafluoroethylene), poly(tetrafluoroethylene)/elastomer, elastomer and fibrous elastomers.

Tu, col. 2, ll. 31–35. This is not a teaching or suggestion of the '844 Patent's copolymer-coated drug-eluting stent.

Ignoring all of these discrepancies, the Board ruled that since a VDF:HFP copolymer with undefined monomer ratio is usable as Tu's optional third elastomer layer, it would have been obvious to use it in the Tuch stent. Neither Tuch nor Tu so suggests. The Board's ruling illustrates the “insidious” exercise of decisional hindsight, whereby that which the inventor taught is used by the decision-maker to reconstruct the invention. This fallacy has long been rejected:

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983).

Tu does not provide substantial evidence for selecting the '844 Patent's copolymer in a vascular stent. The Board acknowledged that neither Tuch nor Tu suggests the 85/15 monomer ratio of vinylidene fluoride and hexafluoropropylene. The '844 Patent demonstrates differences in the properties of various monomer ratios, in that the 85/15 copolymers are “semicrystalline,” and that

copolymers with a 60.6/39.4 ratio are “marketed as elastomers.” ’844 Patent, col. 20, ll. 22–27. This evidence weighs against reliance on the Tu reference to teach the 85/15 copolymer for properties suitable for a vascular stent.

The Supreme Court guides that “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Tu does not fill the gaps in Tuch to render obvious the selection of this specific copolymer and ratio for use in the Tuch stent, for Tu provides no reason for a person of ordinary skill to select the 85/15 copolymer for use in Tuch.

The Lo reference

The Board’s third set of references, represented by Lo, does not shift this balance. The Board cited U.S. Patent No. 3,178,399 (the Lo reference), a 50-year-old patent that shows that the ’844 copolymer in 85/15 ratio was a known product with known uses. Copolymers of vinylidene fluoride and hexafluoropropylene having comonomer ratios similar to the ’844 Patent’s 85/15 ratio are described in the Lo reference as having a

unique combination of tensile strength and reversible elongation properties and are especially suitable as durable, flexible coatings for application to various fabric surfaces. These surfaces may, in a preferred form of application, take the form of protective clothing (for example, as suits, boots, gloves, helmets and other wearing apparel) and other articles of manufacture which are comprised of exposed surfaces which may be subjected to bending, folding, or other forms of distortion in the course of performing their function under special environmental conditions. They may also be used in film form (either oriented or unoriented)

e.g. in electrical tapes, magnetic recording tapes, etc., and as protective coatings on tanks, storage vessels and the like.

Lo, col. 10, ll. 27–39. None of these uses has any relation to a vascular stent or any biological application. However, from Lo's uses as boot and helmet coatings and electrical tapes, the Board stated that “Lo describes copolymers of vinylidene fluoride (VDF) and hexafluoropropylene (HFP) which have flexibility, elasticity, and extensibility,” Board Op. at 5, and from this selection out of context the Board extracted obviousness of use in a drug-eluting vascular stent. Lo's range of uses of this known copolymer, undifferentiated as to monomer ratio and copolymer properties, does not fill the gaps in Tuch and Tu to suggest use for a drug-eluting vascular stent.

The Board erred in its analysis, collecting the elements of the '844 Patent's stent from assorted sources, and placing them in the template of the '844 claim. The only guide to this reconstruction is the '844 Patent itself. *See Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”). The Court has reinforced that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art.” *KSR Int'l Co.*, 550 U.S. at 418–19. Neither the record nor the law supports the Board's conclusion that a person of ordinary skill would be motivated to select this Lo copolymer for use in a vascular stent.

The objective evidence

The “secondary considerations” are part of the obviousness determination. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966) (“Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to

give light to the circumstances surrounding the origin of the subject matter sought to be patented.”); *W.L. Gore*, 721 F.2d at 1555 (objective evidence “should when present always be considered as an integral part of the analysis.”).

The Board erred in declining to consider the evidence of copying, commercial success, and medical acclaim. Such evidence “may often be the most probative and cogent evidence in the record.” *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983), for the objective evidence reflects the “temporal and technical perspective” of the invention. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012).

This evidence must be considered along with the entirety of the evidence. *Stratoflex*, 713 F.2d at 1538–39 (objective evidence “is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.”); *In re Mageli*, 470 F.2d 1380, 1383 (C.C.P.A. 1973) (“[E]vidence bearing on the facts is never of ‘no moment,’ is always to be considered, and accorded whatever weight it may have.”). The response of the marketplace, and copying by competitors, may evidence the improved technology and beneficial properties of an invention. Ethicon’s expert Dr. Mikos described the advantages of the ’844 Patent’s stent over the available drug-eluting stents, and the apparently undisputed copying by the competitors who brought this *inter partes* reexamination. Mikos Decl. at 38–39. Dr. Mikos testified:

Data on file at Abbott Vascular and relied upon by Abbott in its FDA submissions shows that the PVDF-HFP coated Xience V stent is more thromboresistant (i.e., shows greater tendency to reduce thrombus formation) than other drug-eluting stent coatings.

Mikos Decl. at 39. He stated, “numerous clinicians have also emphasized that the PVDF-HFP polymer used in the

Xience V stent shows unexpectedly less inflammation.” *Id.*

The Board declined to consider the evidence of superior properties and commercial success, stating:

This evidence is not persuasive since it does not establish that the reduction in inflammation observed with Xience V is in comparison with the closest prior art as required under *Baxter*, 952 F.2d at 392. Rather, it appears the news articles are reporting that Xience’s polymer is less inflammatory than the polymers on existing stents.

Board Op. at 14.

The Board did not identify what it deemed to be an acceptable prior art comparison, except to state that “Patent Owner has not provided sufficient testimony that this reduced inflammation would have been unexpected by one of ordinary skill in the art in comparison to the polymers described in Tuch, for example, which teaches stents with polymer coatings, including a homopolymer of VDF (Tuch6).” Board Op. at 14. The Board did not mention the comparative data in the ’844 Patent, which compared the 85/15 copolymer with stents coated with the polyvinylidene fluoride (VDF) homopolymer. ’844 Patent, col. 19, ll. 22–48. The data in the specification showed that the polyvinylidene fluoride homopolymer “adhered poorly to the stent and flaked off, indicating they were too brittle” when dried at the low temperatures required by the ’844 Patent. ’844 Patent, col. 19, ll. 36–41.

The ’844 Patent also included comparative data with copolymers of vinylidene fluoride and hexafluoropropylene in 92/8 and 91/9 weight percent ratios, and showed the superior results obtained with the 85/15 ratio. ’844 Patent, col. 19, ll. 24–28, 36–41. The ’844 Patent also compared the 85/15 copolymer with copolymers having a 60.6/39.4 ratio, which were “marketed as elastomers.”

'844 Patent, col. 20, ll. 22–24. Those copolymers, when mixed with rapamycin and dried at the claimed temperature, produced “a white film, indicating phase separation of the drug and the polymer.” '844 Patent, col. 20, ll. 55–60. In contrast, with the 85/15 copolymer “a clear coating, indicating a solid solution of the drug in the polymer, is obtained.” '844 Patent, col. 20, ll. 53–55. Additional comparative data in the '844 Patent showed differences in the fraction of drug released over time between the claimed 85/15 copolymer and the 60.6/39.4 copolymer of vinylidene fluoride and hexafluoropropylene without a topcoat. '844 Patent, Figs. 3 and 5; col. 21, ll. 9–24.

These comparisons are evidence of unpredicted results. “Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results.” *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). The Board’s refusal to consider this evidence, instead criticizing the “absence” of comparisons with some undefined prior art, is untenable.

SUMMARY

The references cited by the Board provide no teaching or suggestion or motivation to select the specific copolymer and ratio of the claimed '844 Patent's vascular stent, and no basis for expecting that this composition would produce the advantageous properties that are obtained. The Tuch list of stent materials does not lead to selecting the omitted copolymer of 85% vinylidene fluoride and 15% hexafluoropropylene. The Tu multi-layered fabric for medical grafts does not fill this gap in Tuch. And Lo, if anything, leads away from the '844 Patent, for the Lo products are not analogous to vascular stents. No combination of references suggests utilization of the '844 Patent's copolymer in drug-eluting vascular stents.

Substantial evidence does not support the Board's findings and conclusion that a person of ordinary skill in the field of this invention would obviously select the '844 Patent's copolymer from its omission in Tuch, from the multilayered fabrics of Tu, and the non-analogous uses in Lo. From the court's contrary ruling, I respectfully dissent.