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Federal Circuit Patent Bulletin: *In re Ethicon, Inc.*

January 3, 2017

"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."

On January 3, 2017, in *In re Ethicon, Inc.*, the U.S. Court of Appeals for the Federal Circuit (Newman, Lourie,* Dyk) affirmed the U.S. Patent and Trademark Office Patent Trial and Appeal Board *inter partes* reexamination decision upholding the patent examiner's rejection of certain claims of U.S. Patent No. 7,591,844, which related to intraluminal medical devices for the local delivery of drugs (*e.g.*, drug-eluting stents), and methods for maintaining drugs on those devices involving polyvinylidenefluoride (VDF) and hexafluoropropylene (HFP). The Federal Circuit stated:

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. 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." 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." Similarly, § 103 likely bars patentability unless "the improvement is more than the predictable use of prior art elements according to their established functions." Generally, a skilled artisan would only have been motivated to combine analogous art. Prior art is analogous

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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." . . .

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. 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," and apply "an expansive and flexible approach" to obviousness.

Here, the Board made sufficient factual findings under the circumstances to support its obviousness conclusion and those findings are supported by substantial evidence. Tuch [(U.S. Patent No. 5,824,048)] teaches that the polymer must be "biocompatible." 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. 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." 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 [(U.S. Patent No. 4,816,339)] and Lo [(U.S. Patent No. 3,178,399)] 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, and lists VDF:HFP first in its list of preferred elastomers. Lo similarly teaches VDF:HFP copolymers with "varying degrees of flexibility, elasticity and extensibility," and that a weight ratio of 85:15 VDF:HFP achieves the optimal combination of tensile strength and reversible elongation. 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. . . .

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," and lists VDF as an example of a suitable biostable polymer. Although Tuch states that a "bioabsorbable polymer is probably more desirable," this statement, absent clear discouragement from use, does not compel a finding that Tuch teaches away from using VDF:HFP as a stent coating.

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," 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," and an alternative embodiment where the "combination of layers provides for better hydrophilicity due to the elastomer in the luminal layer."

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 . . . ." The Board relied on Lo for "teaching the properties of VDF: HFP" at different ratios of copolymer. Substantial evidence supports finding that Lo's teachings are at least "reasonably pertinent to the particular problem with which the inventor is involved," 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.

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." Ethicon presented no evidence of a long-felt need or the failure of others.