

IN RE ETHICON, INC., Appeal No. 2015-1696 (Fed. Cir. January 3, 2017). Before Newman, Lourie, and Dyk. On appeal from Patent Trial and Appeal Board.

Background:

Ethicon sued Abbott and Boston Scientific (Requesters) in a U.S. district court for patent infringement of a patent drawn to a vascular drug-eluting stent, the gist of which is a coating comprising a particular copolymer made of an 85:15 monomer ratio of vinylidene fluoride (VDF) and hexafluoropropene (HFP) (85:15:VDF:HFP). Each of the Requesters then filed separate requests for *inter partes* reexamination, alleging invalidity, which requests were merged.

During the reexamination, the Examiner rejected the claims on grounds of obviousness based on a patent to Tuch in view of patents to Tu and to Lo. In defending its patent, Ethicon relied on various objective indicia of nonobviousness, including commercial success, and copying by and industry praise for certain stents sold by the Requesters, backed up by testimony of an expert, and comparative data showing unexpected results, between their copolymer and similar copolymers and a homopolymer of VDF. The Examiner maintained his rejection. Ethicon appealed to the PTAB (Board).

The Board, in affirming the Examiner, found that Tuch disclosed a list of polymers for such coatings including "vinyl halide polymers and copolymers" with a homopolymer of VDF listed as an example, that polymers for such coatings should be biostable or bioabsorbable, and that elasticity was a problem. The Board relied on Tu for a disclosure of a VDF:HFP copolymer listed first in a list of potential elastomers for Tu's invention, drawn to particular implantable medical devices but not stents, and found that such copolymer has biocompatibility and elasticity. The Board relied on 50-year old Lo for a disclosure of VDF:HFP of various ratios, including 85:15, as having various properties including elasticity. The Board found that none of Ethicon's evidence of nonobviousness was entitled to substantial weight. Particularly, the Board found the evidence insufficient to show that the commercial success, industry praise and unexpected results were due to the use of 85:15:VDF:HFP. Finally, the Board, cited *KSR International Co.v. Teleflex Inc.*, 550 U.S. 398 (2007), in support of the holding of obviousness.

Ethicon then appealed to the Federal Circuit. During the appeal, the Requesters withdrew and the PTO Director intervened to defend the Board's decision.

Issue/Holding:

Did the Board err in affirming the rejection of the Examiner? No.

Discussion:

In the court, Ethicon challenged the Board's factual findings regarding the applied references and the ultimate conclusion of obviousness. The Director responded that the findings were supported by substantial evidence. The court, in essence, in agreeing with the Director's arguments, adopted the Board's findings.

Judge Newman dissented, finding that Tuch's disclosure of applicable monomers (none of which were HFP) encompassed thousands of polymers and copolymers, and neither Tu nor Lo disclosed or suggested VDF:HFP copolymers as stent materials. The dissent added that the elastomer of Tu is in an optional third layer and that the elasticity that the Court majority found in analyzing Tu was due to arrangement of the layers, not the material of the optional third layer. The dissent further added that Lo's disclosure of VDF:HFP copolymers, which were with regard to durable, flexible coatings for application to various fabric surfaces, preferably protective clothing, would not have suggested use in stents. Finally, the dissent found that neither the Examiner nor the Board gave sufficient weight to the evidence of nonobviousness.