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In This Issue

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Federal Circuit, *Inter Alia*, Reverses District Court Finding Of Indefiniteness And Noninfringement Of Ethicon Utility Patents

In the appeal from the U.S. District Court for the Southern District of Ohio in *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, the Court of Appeals for the the Federal Circuit ("CAFC"), *inter alia*, reversed the District Court's finding of: (i) invalidity for indefiniteness of U.S. Patent No. 8,182,501 ("the '501 patent"); and (ii) noninfringement of U.S. Patent No. 5,989,275 ("the '275 patent").

The asserted Ethicon utility patents are directed to surgical instruments that use ultrasonic energy created by high frequency vibrating blades to cut tissue and blood vessels, and when pressed against the blood vessel walls, the vibrating blades cause blood to coagulate thereby sealing the blood vessels and preventing bleeding. Both Ethicon and Covidien develop and market such devices. After Covidien launched a competing line of ultrasonic surgical equipment, Ethicon filed suit alleging infringement of the '501 patent and the '275 patent. After the close of discovery, the District Court granted summary judgment finding, *inter alia*, the '501 patent is invalid as indefinite and the '275 patent not infringed. Ethicon appealed.

Each of the asserted claims of the '501 patent includes a limitation requiring clamping pressure values in a range. The asserted claims specifically recite either an "average" clamping/coaptation pressure or simply a "clamping pressure." The '501 patent specification uses "clamping pressure" interchangeably with "average" clamping/coaptation pressure, and describes the "exert coaptation pressure" step as the exertion of "an average coaptation pressure on the blood vessel between and including 60 psi and 210 psi."

The District Court held the asserted claims of the '501 patent invalid as indefinite on the grounds that nothing in the specification or in the state of the art specified "a method of measurement, the location of measurement, and the type and amount of tissue used for the measurement of clamping forces and clamping pressures." The District Court further noted that "measuring at different locations along the clamp arm provided different force and pressure values" and "when the clamp arm was fully engaged with tissue, the tissue could be thin or thick, stiff or compressible, and depending on the type of tissue, the measurement of the clamping force and pressure would differ."

On appeal, Ethicon argued that the District Court ignored the proffered evidence and improperly resolved disputed issues in favor of movant

Covidien. Ethicon further argued that one skilled in the art reading the '501 patent specification would understand that the clamping force measurements recited in the claims must be made when the clamping arm and blade are in a closed position, and in a manner that reflects the average pressure applied by the clamping arm on the clamping surface, which can be measured at the midpoint of the recited clamping surface area.

The CAFC agreed with Ethicon, noting that a finding of indefiniteness was reviewed *de novo* and only proper where a claim, when read in light of the specification and prosecution history, failed to inform skilled artisans about the scope of the invention with reasonable certainty. The CAFC also observed that the '501 patent specification made clear that the claimed clamping or coaptation pressure on the blood vessel is an average pressure that should be measured when the clamping arm and the blade are in a closed position and exerting pressure on a blood vessel disposed between them.

The CAFC further discussed that, although the '501 patent specification disclosed four (4) techniques to measure pressure, the District Court ignored expert testimony that each of these methods was designed to provide the same clamping force measurement, and that while there may have been slight variation(s) between the methods, any variation(s) are simply due to natural variances in real-world testing conditions. The CAFC ultimately concluded that the definiteness requirement of 35 U.S.C §112 only requires that one skilled in the art must be able to understand which pressures are relevant to the claims and how these pressures are to be measured, so as to discern the scope of the claimed average pressure, and that if these requirements are satisfied—there is no requirement for the specification to identify a particular measurement technique. The CAFC accordingly reversed the District Court's summary judgment of indefiniteness.

The '275 patent similarly claims a particular configuration of an ultrasonic surgical shears device that generates and then propagates ultrasonic energy to the clamping end of the device while dampening undesired vibrations. Only vibrational motions directly forward and backward along the transmission rod axis towards the blade and clamping arm are desirable because transverse motion can lead to suboptimal performance; to reduce undesirable transverse vibrational motion, the device includes a damping sheath that "loosely surrounds" the transmission rod.

After the close of discovery, Covidien also filed a summary judgment motion seeking noninfringement of the asserted claims arguing that the damping sheath surrounding the transmission rod of its shears is not "configured to loosely contact" the transmission rod or "adapted to absorb undesired vibrations." The District Court construed "configured to loosely contact" as "structured to have contact other than at fixed support points, but not tightly fitted" and granted summary judgment of noninfringement.

On appeal, Ethicon asserted that: (i) the District Court improperly imported a limitation into the term inconsistent with its ordinary meaning improperly resolved issues of fact and conflicting expert testimony in Covidien's favor; and (ii) "loose contact" is contact "other than at fixed support points." .

In finding for Ethicon, the CAFC observed that the claims recite that the

damping sheath surrounding the transmission rod "loosely contacts the transmission rod over a portion of the transmission rod," and that the recitation of "over a portion" suggests that such "loose contact" is not contact only at discrete fixed points. The CAFC further observed that the '271 patent specification reinforces an understanding that a longitudinal slit extends along the damping sheath from one end to the other in order to allow the sheath to fit over the transmission rod, and that without this slit, the damping sheath "may not be able to loosely contact the transmission rod" over its cross-sectional diameter.

The CAFC then noted that there was contradictory expert testimony as to whether the sheath of the accused device would "loosely contact" the transmission rod, and that the District Court's finding did not take into account contrary evidence from Ethicon's expert showing that the sheath of Covidien's accused shears appears to contact the transmission rod at points other than the nodal ribs during operation. Given the contradictory expert testimony, the CAFC, taking all inferences in favor of non-movant Ethicon on motion for summary judgment, vacated the District Court's finding of noninfringement.

Federal Circuit Clarifies That The Presumption Of Patent Validity Does Not Apply In An *Ex Parte* Reexamination

In *Dome Patent L.P. v. Lee*, the CAFC clarified that when the U.S. Patent and Trademark Office ("USPTO") institutes an *ex parte* reexamination, the prosecution is "reopened" to determine whether the claimed subject matter should have been allowed in the first place, such that the presumption of validity for an issued patent is no longer applicable.

Dome's U.S. Patent No. 4,306,042 ("'the '042 patent") issued in 1981 and expired in 1998. In December 1997, Dome sued six parties for infringement of the '042 patent, and one of the defendants sought an *ex parte* reexamination, which was granted in 1999; the District Court stayed the lawsuit pending resolution of the reexamination. The USPTO issued the reexamination certificate in 2007 finding several claims patentable, but cancelling independent claim 1 as obvious under 35 U.S.C. § 103. Thereafter, Dome filed a Section 146 action in the U.S. District Court for the District of Columbia challenging the USPTO's findings, and the District Court affirmed.

Dome then appealed to the CAFC, arguing that the District Court erred in affirming the finding of obviousness because the USPTO applied a "preponderance of the evidence" standard, and not the more onerous "clear and convincing evidence" standard. Dome specifically asserted that, while the USPTO need only show unpatentability by a preponderance of the evidence in reexamination, this was a different situation because the '042 patent was an issued patent such that the statutory presumption of validity applied requiring application of the "clear and convincing" standard per typical patent litigation practice.

The CAFC affirmed the District Court, noting that "[w]hen the Patent Office

institutes ex parte reexamination, it reopens prosecution to determine whether the claimed subject matter should have been allowed in the first place. At that point, there is no need to presume that the Patent Office had 'done its job' in the previous examination. Accordingly, the presumption of validity is no longer applicable."

The CAFC observed that this conclusion aligns with the purpose of reexamination, including allowing the USPTO to take a second look at patents thought "doubtful," And that "[i]n a very real sense, the intent underlying reexamination is a 'start over.'" The CAFC then held that this intent would be hindered if a district court was required to presume that a reexamined claim is valid simply because of the USPTO's previous determination, which would inappropriately impose a burden on the USPTO to defend its own subsequent decision of invalidity on reexamination decision by clear and convincing evidence.