

Keywords: JMOL; waiver of infringement under doctrine of equivalents; pleading inequitable conduct

EXERGEN CORPORATION v. WAL-MART STORES, INC. et al.

(Fed. Cir. 2008)

Decided August 4, 2009

I. Facts

Exergen sued SAAT for infringement of three patents related to infrared thermometers for measuring human body temperature. The thermometers first detect infrared radiation from the surface of the human body, such as the ear drum or the forehead, to obtain the surface temperature. The surface temperature is a function of both the internal temperature of the body and the ambient temperature, so the thermometers may calculate the internal temperature using equations provided in the patents and then display a digital readout of the internal temperature. Two of the patents in suit disclose a thermometer that detects radiation from the eardrum, but the claims of those patents are directed more broadly for detecting radiation from “biological tissue.” The remaining patent is directed to a thermometer that detects radiation from the skin that covers the temporal artery in the temple region near the side of the forehead.

SAAT manufactures thermometers that detect radiation from the skin that covers the temporal artery. The SAAT thermometers then convert the measured surface reading to the patient’s oral temperature.

Exergen brought suit against SAAT in 2001, and SAAT sought leave to amend its pleadings to amend inequitable conduct as an affirmative defense and counterclaim against two of the patents about a year later. The trial court denied SAAT’s motion, stating that the proposed pleading failed to allege inequitable conduct with particularity as required under FRCP rule 9(b). The court then conducted the hearing on the claim construction, and, before trial, Exergen waived any argument that SAAT infringed under the doctrine of equivalents. The case proceeded to a jury trial on the case of literal infringement only, and the jury found that SAAT directly infringed claims of two of the patents in suit and actively induced infringement of claims of the remaining patent. The jury further found that the infringement of each patent to be willful and found in favor of Exergen on SAAT’s invalidity defenses. Subsequently, SAAT moved for JMOL *inter alia* on the grounds of non-infringement and invalidity. The motion was denied, and Exergen and SAAT both appealed.

II. Issues

- A. Should the trial court have granted SAAT’s motion for JMOL on invalidity?
- B. Should the trial court have granted SAAT’s motion for JMOL on non-infringement?
- C. Did the trial court properly deny SAAT’s motion for leave to amend to add an inequitable conduct claim?

III. Discussion

- A. Yes. The trial court should have granted SAAT’s motion for JMOL regarding invalidity. SAAT had alleged that a prior art reference anticipated the asserted claims of one of the patents in suit. The sole independent claim is reproduced below:

1. A method of detecting temperature of biological tissue comprising:

providing a radiation detector for sensing infrared radiation from an external target;

sensing radiation from multiple areas of the biological tissue with the radiation detector; and

electronically detecting the peak radiation from the multiple areas to obtain a peak temperature signal.

The prior art reference disclosed a hand-held probe unit containing an infrared sensing thermopile detector along with a base unit that mates and heats the probe unit. When a user removes the probe unit from the base unit, the system begins taking radiation measurements at a rate of seven times per second and stores the maximum reading. From the time that the probe unit is removed from the base unit, the user has ten seconds to insert to probe into the external ear canal and press the scan key. When the scan key is pressed, the maximum reading from the beginning of the removal of the probe unit from the base unit is displayed as the temperature of the ear drum. Exergen's expert admitted at trial that the reference discloses all the limitations of the claim except for the third step, and on appeal, Exergen only focused on the third step to distinguish the claim over the prior art reference. First, Exergen argued that the reference heats the probe and detects the radiation in addition to the radiation from the probe, and second, the reference detects radiation only from a single spot and not from multiple areas as claimed.

On appeal, the Federal Circuit noted that nothing in the claim requires the detector to detect radiation solely from the biological tissue, and particularly noted that use of the use term "comprising" in the claim as requiring the claim to be open-ended. The Federal Circuit also found that Exergen's contention that the reference detects radiation only from a single spot, and not from multiple areas, was unsupported by substantial evidence. The Federal Circuit relied on Exergen's expert to testify that the reference inherently discloses this limitation because the probe unit is constantly measuring infrared radiation from the time it is removed from the patient until the time it is inserted into the patient's eardrum, plus measuring radiation along the patient's face and other areas. Because substantial evidence supported a finding of invalidity, the Federal Circuit reversed the jury's findings that the claims were not invalid.

B. Yes. The trial court should have granted SAAT's motion for JMOL on infringement. The following claim was found to be infringed:

7. A radiation detector comprising:

a thermopile mounted to view a target of biological surface tissue;

a temperature sensor for sensing ambient temperature;

an electronic circuit coupled to the thermopile and temperature sensor and responsive to the voltage across the thermopile and the temperature sensed by the sensor to provide an indication of an internal temperature within the biological tissue adjusted for the ambient temperature to which the surface tissue is exposed; and

a display for providing an indication of the internal temperature.

SAAT argued that its device does not possess a display for providing an indication of the internal temperature. The district court misconstrued "internal temperature" to mean "temperature of the region existing beneath the surface of the biological tissue targeted

for measurement.” Neither SAAT nor Exergen challenged this construction. It is undisputed that SAAT’s device targets the patient’s forehead area, so the relevant “internal temperature” is the temperature of the temporal artery beneath the skin of the forehead. However, SAAT’s device measures the infrared radiation from the patient’s forehead to calculate and display a digital readout of the patient’s *oral* temperature, which is different than the patient’s temporal artery temperature. Although Exergen argued that oral temperature is an internal temperature and that it is an “indication” of internal temperature because the two temperatures could be compared and correlated to one another, the Federal Circuit was not swayed. Instead, the Federal Circuit found that once a district court has construed the relevant terms of a claim, the legal determination governs for the purposes of trial and no party may contradict the court’s construction to a jury. Therefore, the Federal Circuit found substantial evidence that the SAAT device did not infringe the claim.

Further, with regard to the jury finding that SAAT actively induced infringement of the claims of one of the patents in suit, the Federal Circuit found that any customer that actually followed SAAT’s instructions would not have performed the steps recited in the claims and thus would not have directly infringed the patent. Specifically, the independent claim at issue recites:

1. *A method of detecting human body temperature comprising:
laterally scanning a temperature detector across a forehead; and
providing a peak temperature reading from plural readings during
the step of scanning.*

The parties agreed that “laterally” means “horizontal relative to the human body.” However, the instructions relating to the SAAT thermometers stated: “scan with the thermometer around the temple area (marked as dotted area in the drawings)” and “place the thermometer’s soft touch tip just outside the eyebrow (in the temple region of the forehead) and slowly slide upwards to just below the hairline.” Thus, SAAT argued that a user following either set of instructions would not be “laterally scanning ... across the forehead.” Exergen responded that each oval pattern includes at least some horizontal component, which Exergen believed was sufficient to constitute “laterally scanning.” The Federal Circuit agreed with SAAT and found that Exergen’s argument ignored the clear claim language. In fact, the Federal Circuit noted that Exergen attempted to “wood-sniff” this language out of the claim in an argument “sounding in the doctrine of equivalents,” an argument that Exergen expressly waived before trial. Hence, the Federal Circuit found that no reasonable jury could have found that scanning using an oval pattern in the temple region on one side of the forehead could meet the literal requirement of scanning laterally across a forehead.

- C. Yes, the trial court should have denied SAAT’s motion to amend its pleadings to add inequitable conduct. The relevant portions of SAAT’s pleading states:

40. *The ‘685 patent is unenforceable due to inequitable conduct by Exergen, its agents and/or attorneys during the prosecution of the application for the ‘685 patent before the PTO.*
41. *Prior to the filing of the ‘685 patent application, Exergen filed a patent application that ultimately issued as .S. Patent No. 4,566,808 (hereinafter referred to as “the ‘808 patent”) on January 28, 1986. Thus, Exergen was aware of the ‘808 patent well before the ‘685 patent issued on September 18, 2001. The ‘808 patent was material to the patentability of the ‘685 patent because it discloses a technique of scanning*

a radiation detector across a target to measure the maximum emitted radiation, and it is not cumulative to the information already of record in the prosecution history of the '685 patent.

42. *In addition, U.S. Patent No. 4,317,998 (hereinafter referred to as "the '998 patent") was cited in a Supplemental Information Disclosure Statement filed by Exergen on October 17, 1997 in connection with the prosecution of the '205 patent. Thus, Exergen was aware of the '998 patent well before the '685 patent issued on September 18, 2001. the '998 patent was material to the patentability of the '685 patent because it discloses a technique of swiping a radiation detector across a target, and it is not cumulative to the information already of record in the prosecution history of the '685 patent.*
43. *Because Exergen was aware of the '808 patent and the '998 patent prior to the issuance of the '685 patent, Exergen had an opportunity to disclose each of these patents to the PTO during the prosecution of the '685 patent. Moreover, because the '808 patent and the '998 patent were material to the patentability of the '685 patent, Exergen had an obligation to disclose each of these patents to the PTO. Nevertheless, Exergen failed to cite either of these patent to the PTO during the prosecution of the '685 patent. SAAT is informed and believes, and therefore alleges, that Exergen, its agents and/or attorneys intentionally withheld the '808 patent and the '998 patent from the PTO with the intent to deceive the PTO to issue the '685 patent.*
44. *In addition, during the prosecution the '685 patent application, Exergen made a number of arguments to the PTO to overcome rejections of the pending claims based upon various prior art references related to tympanic temperature detectors. For example, in an Amendment filed on July 31, 2000, the following statements were made to the PTO:*

What was non-obvious ... was that reliable temperature measurements could be obtained from the forehead by extending techniques initially developed for the tympanic membrane. What had not been generally appreciated by those skilled in the art of temperature measurement was that the superficial temporal artery ... provides an exceptionally reliable temperature reading.

45. *These arguments made to the PTO were contradicted by statements from Exergen's own website, such as the following statement which appeared on the website at the time of the July 31, 2000 Amendment:*

The temporal artery area has a long history of temperature measurement, dating back to the early centuries before Christ with the first recorded

references to palpation of the head for fever assessment.

46. *Thus, while Exergen acknowledged on its website that the temporal artery has a long history of temperature measurement, Exergen misrepresented to the PTO that no such history existed and omitted any reference to the website. The misrepresentation and omission were material to the patentability of the '685 patent because the information was not cumulative to the information already of record in the prosecution history of the '685 patent, and it refutes, or is inconsistent with, a position taken by Exergen in asserting an argument of patentability. SAAT is informed and believes, and therefore alleges, that the misrepresentation and omission were made with the intent to deceive the PTO to issue the '685 patent.*

SAAT argued that its allegations passed muster under the 1st Circuit's "time, place, and content" test for Rule 9(b) pleadings. However, the Federal circuit noted that it applies its own law and not the law of the regional circuit to the question of whether inequitable conduct has been pleaded with particularity. Rule 9 requires that all averments of fraud or mistake "shall be stated with particularity." A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b). The substantive elements of inequitable conduct are (1) an individual associated with the filing and the prosecution of a patent application made an affirmative misrepresentation of the material fact, failed to disclose material information, or submitted false material information and (2) the individual did so with specific intent to deceive. The Federal Circuit determined that Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation committed before the PTO. Further, the Federal Circuit noted that Rule 9 also states that the intent of a person may be averred generally and that the pleadings thus require sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.

Turning to SAAT's pleading, the Federal Circuit agreed with the district court that the allegations are deficient with respect to both the particularity of the facts alleged and the reasonableness of the inference of *scienter*. First the Federal Circuit noted that the pleading generally refers to "Exergen, its agents and/or attorneys," but failed to name the specific individual associated with the filing or the prosecution who knew of the material information and deliberately withheld it or misrepresented it. Thus, the pleading failed to identify the "who" of the material omission or misrepresentation. Second, the Federal Circuit noted that the pleading failed to identify which claims, and which limitations in those claims, the withheld references are relevant to, and where in those references the material information is found. Thus, the pleadings failed the "what" and "where" requirements. Third, the Federal Circuit noted that the pleading states generally that the withheld references or material are not cumulative of the information not already of record, but the pleading did not identify the particular claim limitations that are supposedly absent from the information of record. Such allegations are necessary to explain both "why" the withheld information is material and not cumulative and "how" an examiner would have used this information in assessing the patentability of the claims. Finally, the Federal Circuit noted that the facts alleged do not give rise to a reasonable inference of *scienter*. The pleading provided no factual basis to infer that any specific individual knew of the specific information in the withheld references that is alleged to be material to the claims of Exergen's patents. The Federal Circuit specifically stated that one cannot assume that an individual, who generally knew that a reference existed, also

knew of the specific material information contained in that reference. In regard to the alleged misrepresentation, the Federal Circuit found that none of the alleged facts could lead one to reasonable infer that at the time the allegedly false statement was made, the individual who made the statement was aware of an allegedly contradictory statement on Exergen's website. Finally, with regard to the pleading based on information and belief, the Federal Circuit found that this type of pleading is permitted when essential information lies uniquely in the other party's control, but only if the pleading sets forth the specific facts on which the belief is reasonably based. Here, the mere fact that an applicant disclosed a reference during the prosecution of one application, but did not disclose the reference during the prosecution of a related application, is insufficient to meet the level of deceptive intent required to support allegation of inequitable conduct. Hence, the Federal Circuit upheld the trial court's denial of SAAT's motion to add a claim of inequitable conduct.