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## SUNSTEIN's Federal Circuit Win in *Exergen*: Diagnostic Patents Survive Eligibility Challenge

**BOSTON, MA – March 9, 2018** - The Federal Circuit on March 8 decided the appeal in *Exergen v. Kaz,* affirming nearly all of the $16 million judgment entered in favor of Exergen by the federal district court in Massachusetts. Exergen Corporation, a Watertown, MA-based maker of temporal artery thermometers, had alleged that similar thermometers, sold by Kaz USA, Inc. under the Vicks and Braun labels, infringed two of Exergen's patents. This is the first Federal Circuit decision upholding the patentability of a diagnostic patent since the Supreme Court struck down a diagnostic invention on patent eligibility grounds in *Mayo v. Prometheus* in 2012.

Exergen was represented at the jury trial and on appeal by Sunstein Kann Murphy & Timbers LLP, the Boston-based intellectual property firm. Kerry Timbers was lead counsel.

Kaz had challenged the patent-eligibility of Exergen's invention under 35 U.S.C. § 101, arguing that three key steps underlying Exergen's method and apparatus claims were known in the prior art. But Judge Richard Stearns of the District of Massachusetts found that, though these claim elements may have been known, they had never previously been combined to solve the problem of detecting arterial temperature beneath the skin.

The Federal Circuit affirmed the lower court's conclusion that these claim elements of one of Exergen's patents were not "well-understood, routine, and conventional," a threshold for patent eligibility announced by the Supreme Court in *Mayo*.

The Federal Circuit decided that, even if Exergen's invention is directed to measuring a natural phenomenon, it was "incorporated . . . into an unconventional method of temperature measurement." Exergen's discovery therefore represented an inventive concept, a hallmark of patent-eligibility under the test established by the Supreme Court in *Alice v. CLS Bank* (2014).

The court distinguished Exergen's invention from the diagnostic-test patents the Supreme Court found ineligible in *May*o and in *Ariosa v. Sequenom* (2016), because the methods for determining the existence of a natural phenomenon in those cases were well-known.

The *Exergen v. Kaz* decision notably reinforces very recent Federal Circuit jurisprudence to the effect that whether claim elements are "well-understood, routine and conventional" is a question of fact to which "we must give clear error deference." The court also clarified that "[s]omething is not well-understood, routine, and conventional merely because it is disclosed in a prior art reference."

The court concluded that substantial evidence was lacking to support infringement of a second Exergen patent, so reversed that part of the jury's verdict. This part accounted for only a small percentage of the jury's damages award.

The damages aspect of the Exergen case is noteworthy, as the Federal Circuit upheld a reasonable royalty that amounted to 71% of Kaz's projected net profit (or a per-unit rate of 32%). The jury reasonably based this award, said the court, on expert testimony that the parties were "fierce competitors;" that Exergen had a policy of never granting licenses; that practically every Kaz sale would be a sale lost to Exergen; and that the patent had many more years to run at the time of the parties' hypothetical negotiation.

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