

*Inventorship:
Conception does not Require Scientific Certainty*

University of Pittsburgh v. Hedrick



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Background

- Plaintiffs-Appellees
 - University of Pittsburgh
 - Dr. A.J. Katz and Dr. R. Llull
- Defendants-Appellants
 - M.H. Hedrick *et. al.*
- Appeal from District Court of California
 - ruled Hedrick *et. al.* are not co-inventors
 - granted misjoinder motion to remove the names of Hedrick *et. al.*

Timeline

- Katz and Lull are researchers at Univ. Pitt.
 - 1996 project on de-differentiation of adipocytes (fat cells -> stem cells -> various cells)
 - Late 1996 and early 1997
 - developed methods to isolate the de-differentiated cells
 - Recorded in lab notebook media and protocols that differentiate the cells into other types of cells
 - Ask for help from colleague (electrophysiology) to identify the differentiated neuron
 - Invention disclosure and publication “What’s so Great About Fat?”
 - *“he (Katz) and Lull believed that they had observed cells changing into cells resembling muscle and fat cells”*

Timeline

- Hedrick joined the Pittsburgh team in July 1997 for a 1 year fellowship, during which
 - Katz submitted a research proposal for adipose derived progenitor cells (without Hedrick's name)
 - Hedrick submitted his own proposal for experiment on Katz's progenitor cells
 - Katz, Lull and Hedrick submitted an invention disclosure to Pittsburgh, listing the first date of conception as Oct 1996
- June 1998, Hedrick returned to UCLA
 - Continue on research of the adipose derived cells

Timeline

- Provisional patent claiming method of differentiating adipose derived cells in Mar 1999
- Converted into international application in Mar 2000
- US Patent 6,777,231 claim 1
 - An isolated adipose-derived stem cell that can differentiate into two or more of the group consisting of a bone cell, a cartilage cell, a nerve cell, or a muscle cell.
- October 2004, Pittsburgh filed a request to remove the names of Hedrick *et. al.* as inventor.

Principles to Apply

- Burroughs Wellcome Co. v. Barr Labs., Inc.
 - Inventorship is *“the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.”*
 - *The test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention*
 - *An inventor need not know that his invention will work for conception to be complete. He need only show that he had the complete mental picture and could describe it with particularity; the discovery that the invention actually works is part of its reduction to practice.*

Principles to Apply

- **Argument by Hedrick**
 - Katz and Lull’s research was inconclusive and high speculative until Hedrick et. al. added their effort.
 - Katz and Lull were required to “know” that the invention contained every limitation of each claim at the time of conception.
- **The CAFC’s opinion**
 - Knowledge in the context of a possessed, isolated biological construct does not mean proof to a scientific certainty that the construct is exactly what a scientist believes it is.
 - Because the district court found evidence that Katz and Lull had formed a definite and permanent idea of the cells’ inventive qualities, and had in fact observed them, it is immaterial that their knowledge was not scientifically certain

Issue on Claim Construction

- “adipose derived”
 - Katz: “derived from fat tissue”
 - Hedrick: “a species of stem cell distinct from the mesenchymal stem cell that is obtainable from bone marrow tissue”
- Hedrick’s construction “is necessary for their claim of inventorship because they alleged that their research proved that the inventive stem cells were in fact distinct from the prior art mesenchymal stem cells.
- The CAFC rejected Hedrick’s argument that Katz’s construction would allow inclusion of prior art mesenchymal stem cell that traveled from bone marrow and lodged in fat tissue.

Conclusion

- Regarding Inventorship
 - Conception does not Require Scientific Certainty
 - Proof that the Invention Works to a Scientific Certainty is Reduction to Practice
- Good Laboratory Practice is Essential
 - Keep proper records of experiments

Questions?

