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This column is a continuation of last month's column regarding licensee due diligence—Who Owns the Patent—and the case of *The University of Pittsburgh v. Hedrick*, Civil Action No. 04-9014 (C.D. Calif. 2008), hereafter "*Pittsburgh*" now on appeal before the Court of Appeals for the Federal Circuit. In *Pittsburgh*, two parties were the original owners of the patent in question, US 6,777,231 (the '231 patent), and each party licensed the patent to a different licensee. Thereafter, the University of Pittsburgh brought suit against the named UCLA inventors to have them removed as inventors on the patent. The District Court held that the UCLA inventors were not inventors of the claimed subject matter and the only inventors were University of Pittsburgh inventors. Thus, the patent was solely owned by the University of Pittsburgh, and only the licensee from that entity had a valid license.

Inventorship is a two-step inquiry: First, the Court construes the claims, and second, the Court determines who conceived of the subject matter of the properly construed claims [*Eli Lilly v. Aradigm Corp.*, 376 F.3d 1352, 1360 (Fed. Cir. 2004).] "[T]o be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention" [*Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997); *Cook Biotech, Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006)].

The first part of the inquiry—claim construction—is crucial, because an alleged contribution must "[find] its way into the defined invention in a claim" to support a claim of co-inventorship [*Eli Lilly*, 376 F.3d at 1362 (co-inventorship requires "contribut[ion] to the invention defined by a claim"); *Trovan v. Sokymat SA*, 299 F.3d 1292, 1307 (Fed. Cir. 2002).]

In early 2007, the District Court in the *Pittsburgh* case rendered its Claim Construction Order in the action. The Court's Claim Construction Order both defined the subject matter whose conception is at issue and resolved several disputes that Defendants apparently intend to attempt to re-litigate at trial. Attempts by the UCLA Inventors to create a nexus between the research they did at UCLA and the invention claimed in the '231 patent were unsuccessful.

For example, with regard to the claim limitations regarding "stem cell" or "multipotent cell" that is the subject of every claim of the '231 patent—the UCLA Inventors asserted that the term required, inter alia, "the ability of a clonal population of the cells to differentiate into at least two developmental pathways." The Court disagreed that cloning was required and construed "stem cell" according to the University of Pittsburgh's proposed construction of the term: "a pluripotent cell that has the capacity to differentiate in accordance with at least two discrete developmental pathways."

The *Pittsburgh* Court held that the term "stem cell" did not require that the cell be "assessed upon the cell's ability to form a clonal population," and construed the term "multipotent cell" in claim 2 to have the same meaning, thereby rejecting the UCLA Inventor's primary effort to introduce their cloning experiments into the claims. The UCLA Inventors also attempted to add a cloning requirement to claim 5 of the '231 patent, which requires a "substantially homogeneous population" of adipose-derived stem cells.

The UCLA Inventors proposed that such term requires "a clonal population of cells," while the University of Pittsburgh urged the Court to define a "substantially homogeneous population" as "consisting essentially of adipose-derived stem cells," but without "a requirement that would suggest the population must be clonal." Consistent with the patent specification, the Court adopted the University of Pittsburgh's construction, holding that the invention of a substantially homogeneous population of adipose-derived stem cells in claim 5 "must include the lipo-derived cells and may only include other non-affective materials, but it does not suggest that the substantially homogeneous cells must be clonal."

Finally, the UCLA Inventors sought to import into the simple term "adipose-derived" additional language reciting that the claimed adipose-derived stem cell is a "species of stem cell distinct from the mesenchymal stem cell that is

obtainable from bone marrow." They did so in an attempt to make relevant their experiments that identified certain differences between the claimed cells and prior cells isolated from bone marrow. The Court rejected this effort as well, construing "'adipose-derived' to mean 'derived from fat tissue' without the added limitation that it be distinct from the mesenchymal stem cell that is obtainable from bone marrow."

The Federal Circuit has been clear in delineating the requirements for conception and inventorship. In its seminal inventorship case, *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, [40 F.3d 1223 (Fed. Cir. 1994)] the Federal Circuit explained that conception is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention" [*Id.* at 1228]. Fundamentally, the court explained, conception is the "mental part of invention" that "occurs in the inventors' minds"—thinking or conceiving of the invention—as distinguished from the physical aspects of making the invention, conducting experiments with the invention, and proving that the invention is what one conceived it to be [*Id.* at 1227–1228, 1230; *Hybritech Inc v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986)].

However, to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when the contribution is measured against the dimension of the full invention [*Cook*, 460 F.3d at 1373].

Conception is the touchstone of inventorship, the completion of a mental part of invention. [*Burroughs*, 40 F.3d at 1228]. It is "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention." [*Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986).]

Conception is complete when "the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." [*Burroughs*, 40 F.3d at 1228.]

Conception occurs on "the date the inventor first appreciated the fact of what he made." [*Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001).]

Conception requires an inventor to be able to define the invention with particularity so as to distinguish it from prior art. [*Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991).] However, the inventor need not use the exact same wording that later appears in the issued patent claims. [*Mycogen Plant Sci. Inc. v. Monsanto Co.*, 243 F.3d 1316, 1336 (Fed. Cir. 2001).]

An inventor may conceive of an invention without establishing whether the invention would work for its intended purpose. [*See Burroughs*, 40 F.3d at 1231; *Board of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys. Inc.*, 487 F.Supp. 2d 1099, 1116–1117 (N.D. Cal. 2007).]

Research that occurs after conception, including research that confirms the operability of an invention or "simply reduces the inventor's idea to practice" does not support joint inventorship. [*Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed.Cir.1998).]

Conception does not require conclusive physical experiments, scientific proof, and confirmation of operability of the concept or idea in the inventors' minds. [*Burroughs*, 40 F.3d at 1227–1228, 1230; *In re Jolley*, 308 F.3d 1317, 1321 (Fed. Cir. 2002).]

Conception is a mental act, so "courts require corroborating evidence of a contemporaneous disclosure that would enable one skilled in the art to make the invention." [*Burroughs*, 40 F.3d at 1228.]

An alleged co-inventor's testimony, or the testimony of the inventor himself, standing alone, cannot provide clear and convincing evidence of conception. [*Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004); *see Ethicon*, 135 F.3d at 1461.] "Independent corroboration may consist of testimony of a witness ... to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor." [*Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171 (Fed. Cir. 2006).]

"Under the 'rule of reason' standard for corroborating evidence, the trial court must consider corroborating evidence in context, making necessary credibility determinations, and assign appropriate probative weight to the evidence to determine whether clear and convincing evidence supports a claim of co-inventorship." [*Ethicon*, 135 F.3d at 1464.]

By April 1997, the two University of Pittsburgh inventors—Drs. Katz and Llull—had the definite and permanent idea, supported by corroborated evidence documented contemporaneously or in subsequent writings that the cells they had isolated from human adipose tissue were capable of differentiating into fat, muscle, bone, and cartilage cells or multiple mesodermal lineages.

Pittsburgh *Court's Findings of Fact*

The media and protocols in Dr. Katz's notebooks would enable one skilled in the field to isolate adipose-derived stem cells and

differentiate them into each lineage claimed in the '231 patent. [*See Burroughs*, 40 F.3d at 1223, 1228.]

Also, by April 1997, Drs. Katz and Llull had the definite and permanent idea that the above noted cells could be passaged 15 times without differentiating. The Court infers conception of this claim limitation from the fact that artisans in the field would have understood the possession of this limitation even in the absence of contemporaneous documentation expressly reciting the limitation by number. [*See Burroughs*, 40 F.3d at 1231–1232.]

In April and October 1997 respectively, Drs. Llull and Katz had the definite and permanent idea, supported by corroborated evidence that the cells they had isolated from human adipose tissue were capable of differentiating into nerve cells.

While Drs. Katz and Llull both expressed a need to explore this possibility further, the Court finds the evidence sufficient to demonstrate conception. [*See In re Jolley*, 308 F.3d at 1321, 1323.]

Dr. Hedrick's exploration of differentiation into nerve cells occurred after Drs. Katz and Llull's conception. Additionally, before Dr. Hedrick's arrival at the University of Pittsburgh, Drs. Katz and Llull had the firm and definite idea that their cells could be cultured in substantially homogeneous populations.

Drs. Katz and Llull had the firm and definite idea that the adipose-derived stem cells were human, could be genetically modified, secreted hormones, and contained cell-surface bound intracellular signaling moiety by April 1997. Artisans in the field would have understood possession of this limitation even in the absence of contemporaneous documentation expressly reciting the limitations. [*See Burroughs*, 40 F.3d at 1231–1232.]

Drs. Katz and Llull defined their invention with particularity so as to distinguish it from prior art; their ideas were supported by corroborated evidence, considered as a whole. [*See Amgen, Inc.*, 927 F.2d at 1206.]

At times, Dr. Katz did not use the exact same wording that later appears in the patent language; however, this is not required for conception. [*See Mycogen*, 243 F.3d at 1336.] It also is immaterial whether they appreciated the legal patentability or novelty of their invention. [*See Dow*, 267 F.3d at 1341.]

The UCLA Inventors' research after the University of Pittsburgh inventors conception confirmed the operability of the invention and included recipes for the induction medium reported in the examples section of the '231 patent. This, however, does not support a claim of co-inventorship since the contributions occurred after conception. [*See Ethicon*, 135 F.3d at 1460.] Also, the examples listed are not specifically noted in the patent claims. [*See Eli Lilly*, 376 F.3d at 1362.]

Clear and convincing evidence demonstrates that Drs. Katz and Llull completed conception of all of the claims of the '231 patent at the University of Pittsburgh prior to Dr. Hedrick's arrival there and/or prior to any of the other Defendants' work at UCLA. Dr. Hendrick was at the University of Pittsburgh for one year. Afterwards, he went to the University of California at Los Angeles (UCLA) and there he established a laboratory, and worked with the other named defendants to further study the adipose derived stem cell invention made at the University of Pittsburgh.

Dr. Hedrick did not contribute to the conception of any of the claims of the '231 patent. The remaining defendants did not contribute to the conception of any of the claims of the '231 patent.

Clear and convincing evidence demonstrates that Drs. Katz and Llull are the sole inventors of the claims of the '231 patent.

In the decision dated June 9, 2008, Judge Consuelo B. Marshall of the US District Court for the Central District of California, Western Division, held that Drs. Katz and Llull are the sole inventors of the '231 patent and that Drs. Hedrick, Benhaim, Lorenz, and Zhu are not inventors. The judge further ordered the US Patent and Trademark Office to correct the inventorship of the '231 patent to reflect that the correct inventors are Adam J. Katz and Ramon Llull, pursuant to 25 U.S.C. § 256.

On July 9, 2008, an appeal to the Court of Appeals for the Federal Circuit (Appeal No. 08-1468) was filed by the UCLA Inventors. The case will be monitored for future columns. The Appellant's Brief is due for filing by October 30, 2008 and the Brief for the Appellee is due by January 15, 2009.

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