

- 1. United States Patent No. 6,777,231 ("the '231 patent"") relates to adiposederived stem cells. Joint Trial Exhibit ("JTX") 59. The claims of the '231 patent are:
 - (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.
 - (2) An isolated, adipose-derived multipotent cell that differentiates into cells of two or more mesodermal phenotypes.
 - (3) An isolated adipose-derived stem cell that differentiates into two or more of the group consisting of a fat cell, a bone cell, a cartilage cell, a nerve cell, or a muscle cell.
 - (4) An isolated adipose-derived stem cell that differentiates into a combination of any of a fat cell, a bone cell, a cartilage cell, a nerve cell, or a muscle cell.
 - (5) A substantially homogenous population of adipose-derived stem cells, comprising a plurality of the stem cell of claim 1, 3 or 4.
 - (6) The adipose-derived stem cell of claim 1, 3, or 4 which can be cultured for at least 15 passages without differentiating.
 - (7) The adipose-derived stem cell of claim 1, 3 or 4 which is human.
 - (8) The cell of any of claim 1, 3 or 4 which is genetically modified.
 - (9) The cell of any of claim 1, 3 or 4, which has a cell-surface bound intercellular signaling moiety.
 - (10) The cell of any of claim 1, 3 or 4, which secretes a hormone. JTX 59 at 18:25-51; Pre-trial Conf. Order at 2-3.
- 2. The '231 patent lists seven inventors. Adam J. Katz, Ramon Llull, J. William Futrell, Marc H. Hedrick, Prosper Benhaim, Hermann Peter Lorenz, and Min Zhu. JTX 59; Pre-trial Conf. Order at 2.

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- 3. For purposes of this case, Drs. Katz, Llull, and Futrell worked only at the University of Pittsburg ("UPitt"). JTX 1148. Dr. Hedrick worked at UPitt from July 1997 to June 1998. He joined the University of California Los Angeles ("UCLA") in July 1998. Tr. Day 3 (1) at 64:22-65:1, 75:1-77:13; Tr. Day 6 (1) at 68:9-69:8. Drs. Benhaim, Lorenz, and Zhu worked only at UCLA. Drs. Benhaim and Lorenz formed a lab with Dr. Hedrick at UCLA in August 1998, and Dr. Zhu joined this lab in June 1999. Tr. Day 6 (2) 32:25-33:18; Tr. Day 7 (2) 34:7-9; Pre-trial Conf. Order at 2.
- 4. Drs. Katz and Llull began working at UPitt in 1993. Tr. Day 2 (1) 53:14-54:11; Tr. Day 1 (1) 20:24-22:5.
- In 1996, Dr. Katz, working with Dr. Llull, began a project in a laboratory at 5. UPitt involving the isolation, culturing, and passaging of cells from human liposuctioned adipose tissue for use in fat transplantations. JTX 50; Tr. Day 2 (1) 60:10-76:9. Drs. Katz and Llull obtained, among other things, mature fat cells ("adipocytes") and certain cells from the liposuctioned tissue's stromal vascular fraction ("SVF"). Tr. Day 2 (1) 66:7-72:13, 78:22-87:12. JTX 49, 50.
- 6. Drs. Katz and Llull invented and obtained a patent for a device to isolate cells from the SVF. JTX 100, 904. Some of Drs. Katz and Llull's isolation procedures varied from those disclosed in the prior art. Tr. Day 5 (1) at 67:5-68:13.
- The Court construed "isolated" in the '231 patent to mean "in an environment 7. substantially free of other cellular or extracellular materials found in adipose tissue." Feb. 13, 2007 Claim Constr. Order at 12.
- During their research, Drs. Katz and Llull observed that under certain 8. conditions, mature adipocytes would transform into more primitive cells that have a fibroblast-like appearance also known as "de-differentiation." JTX 50:50; Tr. Day 2 (1) at 132:12-139:10. They also observed that their dedifferentiated cells could, under certain conditions, "re-differentiate" or

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- transform back into mature adipocytes. JTX 52:27, 52:40; Tr. Day 2 (2) 4:8-9:20.
- 9. Drs. Katz and Llull also isolated and obtained fibroblast-like cells from the SVF tissue of the samples with which they worked and observed that these cells could also, under certain conditions, be caused to transform into mature adipocytes. The evidence demonstrates that Drs. Katz and Llull believed that the cells they obtained from their isolation procedure were the same as those that resulted from dedifferentiation of mature adipocytes. JTX 52:27, 52:40; Tr. Day 2 (2) 4:8-11:21.
- By late 1996, Dr. Katz had used his isolation procedure and described it in 10. terms that a scientist in the field could understand. Tr. Day 5 (1) at 57:20-58:2, 59:12-61:20, 63:15-65¹: JTX 50:5: JTX 51: JTX 59: JTX 100. Dr. Katz's isolation procedure yields isolated adipose-derived stem cells. Tr. Day 5 (1) at 57:20-58:2. Dr. Katz's isolation procedure removed mature adipocytes and other materials such as erythrocytes (red blood cells) found in fat tissue, yielding the stem cells in an environment substantially free of other cellular or extracellular materials found in adipose tissue. Tr. Day 2 (1) at 75:7-83:13, JTX 50, 59. Dr. Katz also isolated adipose-derived stem cells using his patented Auto-Cell Separator, which results in isolated adipose-derived stem cells. Tr. Day 2 (1) 90:25-103:1; JTX 54; JTX 904. Dr. Katz's isolation procedure is set forth in the '231 patent. JTX 59 at 3:9-4:6, 13:45-14:5.
- 11. By April 1997, Drs. Katz and Llull had the idea that their cells from adipose tissue could "transdifferentiate" into multiple mesodermal lineages including bone, cartilage, fat, and muscle. They documented their results

On December 4, 2007, the Court found that pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-95 (1993), that Plaintiffs' expert, Dr. Farshid Guilak's, testimony will assist the trier of fact to understand the evidence or determine the facts that may be in issue in the case. The Court found that Dr. Guilak was qualified to testify as an expert on adiposederived stem cells.

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- contemporaneously by describing the above concept in laboratory notebooks, letters, a January 1997 Invention Disclosure for the "Auto-Cell Separator," and a February 1997 document entitled "What's So Great About Fat?" JTX 49:13, 49:11; JTX 43; JTX 52:41; JTX 100; JTX 535; Tr. Day 5 (1) 59:12-64; Tr. Day 5 (2) 42:5-11.
- By April 1997, Dr. Katz read the literature from Dr. Arnold Caplan and 12. colleagues and drew an analogy from the cells derived from bone marrow to the cells he had harvested from human liposuction tissue. Dr. Katz believed that there were similarities in the ability of the cell type to differentiate into many other cell types and in self-renewal. JTX 49:14-15; JTX 100 at P571; JTX 401; JTX 405; JTX 1150; JTX 507; Tr. Day 5 (1) 49:17-50:6; Tr. Day 2 (1) at 113:5-18; Tr. Day 2 (2) 11:22-14:18, 16:15-17:3, 19:9-20:10, 20:23-24:23, 17:24-18:22, 25:17-28:16, 48:15-51:24; Tr. Day 3 (1) 27:17-28:13, 30:1-3, 30:10-17, 86:18-23; Tr. Day 3 (2) 10:4-13:3.
- Dr. Caplan's cells were understood to differentiate into, among other lineages, 13. bone, muscle, fat, and cartilage; they were also understood to self-renew — to be capable of being passaged at least 15 times without differentiating. Tr. Day 5 (1) 52:4-54:6; Day 2 (1) 113:5-18; Day 2 (2) 11:22-14:18; JTX 401; JTX 405; JTX 1109.
- Dr. Katz testified that Dr. Caplan's cells "looked very much like the cells I was 14. seeing with my own eyes under the microscope of cells that I had harvested from human liposuction tissue." Tr. Day 2 (2) 20:23-21:9, 17:24-18:22; JTX 405.
- Dr. Katz recorded his appreciation of the property of self-renewal on March 20, 15. 1997. JTX 1150; JTX 1109; Tr. Day 3 (1) 24:2-25:3, 29:6-20, 86:18-23; Tr. Day 2 (2) 19:9-20:10, 21:16-24:5; Tr. Day 3 (2) 10:4-13:3.
- Self-renewal is the property of stem cells to grow and culture for extended 16. periods of time. To those skilled in the field in 1997, stem cells were thought

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- to self-renew for at least 15 passages in culture and there was not a single known example of a stem cell that could not have that ability. Tr. Day 5 (1) 49:17-50:6; Tr. Day 2 (1) 113:5-18; Tr. Day 2 (2) 11:22-14:18; JTX 405; JTX 1109.
- During their research, Drs. Katz and Llull observed their cells changing shape 17. and form into cells with characteristics of non-adipose lineages, and, in January 1997, began testing their idea that multipotent stem cells existed in adipose tissue, using the accepted technique of induction media experiments. JTX 52:31, 39, 47; JTX 54:44; JTX 55:7-9, 12; JTX 1147-A-1147F; JTX 55:19; JTX 52:27, 40; JTX 50:17, 24, 27; JTX 54:45; Tr. Day 1 (1) 58:4-59:21, 64:10-11; Tr. Day 1 (2) 8:9-9:6; Tr. Day 2 (1) 122:21-124:3, 125:25-129:22; Tr. Day 2 (2) 4:13-9:20, 11:11-21, 52:22-59:21; Tr. Day 3 (1) 6:3-8:20, 10:19-11:25, 78:16-80:22; Tr. Day 3 (2) 17:19-43:14; Day 4 (2) 59:11-60:8; 61:17-63:15, 64:14-71:7; Day 5 (1) 64:10-65:19, 60:15-61:16, 54:14-55:22.
- The Court construed "multipotent cell" in the '231 patent to mean "a 18. pluripotent cell that has the capacity to differentiate in accordance with at least two discrete developmental pathways." Feb. 13, 2007 Claim Constr. Order at 11.
- Dr. Katz's laboratory entries on 1/20/97, 1/24/97, and 2/6/97 reflect an 19. induction media experiment to differentiate his cells into muscle. JTX 52:31, 39, 47; Tr. Day 2 (2) 52:22-59:21; Tr. Day 3 (1) 6:3-8:20. The induction media used was different from that disclosed in the '231 patent. Id.
- There is no reason for Drs. Katz and Llull to have conducted the induction 20. media experiments except to confirm or support their conceived idea that the adipose-derived cells they had isolated were multipotent stem cells. Tr. Day 5 (1) 64:10-15; 60:15-61:20; 54:14-55:22; Tr. Day 1 (2) 61:19-62:8; Tr. Day 2 (1) 123:12-126:7. Some of Dr. Katz's experiments yielded inconclusive results. Tr. Day 3 (1) at 11:6-9; Tr. Day 4 (1) at 26:16-20.

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- The media and protocols recorded in Dr. Katz's laboratory notebooks are 21. known to differentiate adipose-derived stem cells into bone, muscle, fat, cartilage, and nerve cells. Tr. Day 5 (1) 63:15-25, 60:15-61:20; Tr. Day 5 (2) 14:8-17:7. Dr. Katz's laboratory notebooks would have enabled a scientist skilled in the field to isolate Dr. Katz's adipose-derived stem cells and differentiate them into each of the lineages claimed above and in the '231 patent. Tr. Day 5 (1) 57:20-61:20, 63:15-25, 60:15-61:20; Tr. Day 5 (2) 14:8-17:7.
- In April 1997, Dr. Llull observed and documented the cells that he and Dr. 22. Katz had isolated from fat tissue changing into cells resembling a nerve cell, a muscle cell, and a fat cell. Dr. Llull emailed a colleague regarding his idea that the adipose-derived cells could differentiate into nerve cells. Specifically, Dr. Llull stated, "[w]e are enormously intrigued by these cells ... specifically, I thought of you because we have several forms that do resemble those of a neuron ... we are eager to find out if they could behave like cytoplasmic bodies for electricil stimuli ... in other words: can we document transmission of an action potential by using your electrophysiological techniques?" JTX 540; JTX 44, 44-A; Day 1 (2) 20:13-36:8, 42:20-44:19, 43:18-44:13, 39:3-41:5, 89:23. In October 1997, Dr. Katz's observed differentiation of his adiposederived cells into nerve cells and documented his observations in his notebook and in slides. JTX 55:15, 45-47; JTX 45-A; JTX 45-B; Tr. Day 3 (1) 31:12-42:1: Tr. Day 3 (2) 55:20-57:1. In one notebook entry, there is a question mark before "nerve cell." Dr. Katz testified that the question mark means "let's do further studies ... to substantiate ... " Tr. Day 3 (1) 39:3-42:1. The exhibit shows a line running through and a line underneath "nerve cell." Dr. Katz did not cross out or otherwise reject the idea that he had observed differentiation into nerve cells. Id.; JTX 55:47.

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- In February 2000, Dr. Hedrick asked the University of California Office of 23. Technology Transfer to include nerve in the patent application based on a "hypothesis that neuroglial differentiation may be possible." At that point, Dr. Hedrick had not conducted any nerve differentiation experiments. Tr. Day 8 (1) 75:15-80:23; JTX 801. July 2000 was the earliest the REBAR laboratory worked on neuronal differentiation. Tr. Day 8 (1) 75:15-76:4.
- The Court construed "substantially homogenous" in the '231 patent to mean 24. "consisting essentially of adipose-derived stem cells." The term "consisting essentially of is referring to the inventive lipo-derived cells denoting that the invention 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 homogenous population cells must be clonal." Claim Const. Order at 13-14.
- Dr. Katz used the terms "homogeneous population" and "heterogeneous 25. population" as indicators of whether all the cells in a population were the same. JTX 1150; JTX 886; Tr. Day 3 (1) 85:21-86:20; Tr. Day 3 (2) 79:11-83:17; Tr. Day 4 (1) 84:5-88:7.
- The "basic and novel" property of the inventive cells is their ability to 26. differentiate into multiple lineages. Tr. Day 5 (1) 49:14-25.
- Dr. Katz did not believe that the other cells potentially present in his stem cell 27. population materially affected his stem cells' ability to differentiate into multiple lineages. Tr. Day 3 (1) at 86:18-88:8; Tr. Day 4 (2) 82:16-83:7.
- The other materials present in Drs. Katz and Llull's stem cell populations did 28. not materially affect the basic and novel property of their stem cells. Tr. Day 5 (2) at 47:13-50:6; Tr. Day 5 (1) 49:14-25.
- The SVF populations with which Dr. Katz worked at the University of 29. Pittsburg were the same as the PLA populations that Defendants studied at UCLA. Day 7 (1) 93:19-94:4; Day 8 (1) 16:16-17:1.

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- By April 1997, Dr. Katz had the firm and definite idea that his adipose-derived 30. stem cells were human, Tr. Day 2 (2) 5:17-6:2, 20:23-21:9, 38:4-24; could be genetically modified, Tr. Day 3 (1) 52:13-56:6; JTX 52:29; secreted hormones, Tr. Day 3 (2) 13:4-14:21; and contain cell-surface bound intracellular signaling moiety, Tr. Day 2 (1) at 103:1-106:5. These properties were known at the time to scientists in the field.
- In September 1997, Dr. Katz submitted a grant proposal entitled "Development 31. Plasticity of Cells Isolated from Human Adipose Tissue" which summarizes some of the work that he and Dr. Llull had done during the previous year. JTX 62. The proposal describes adipose-derived progenitor cells (AdPCs), the multipotent cells that Drs. Katz and Llull isolated from human fat tissue, stating that "folur lab has developed techniques to harvest, isolate, culture, passage, dedifferentiate, differentiate, and genetically alter ... (AdPCs) in an abundant and efficient manner ... and that AdPCs constitute an unimagined reservoir of multipotent mesenchymal stem cells." The proposal also states that "adipocytes ... transform into fibroblast-like progenitor cells which have the potential to proliferate, secrete angiogenic and extracellular matrix factors." Id; Tr. Day 1 (2) 122:22-124:17, 128:17-130:3; Tr. Day 3 (1) 45:4-47:17; Tr. Day 5 (1) 50:7-11.
- The September 1997 proposal lists Drs. Katz and Llull, as well as non-UPitt 32. researchers Drs. Henry Young and Vincent Li as "other collaborators." The proposal also lists Dr. Futrell. It does not mention Dr. Hedrick anywhere in the document. JTX 62.
- Dr. Hedrick does not appear in Dr. Katz's laboratory notebooks in connection 33. with any of the work at UPitt relevant to adipose-derived stem cells. Tr. Day 3 (1) 65:13-68:19; Tr. Day 4 (2) 83:89-84:14; Tr. Day 7 (1) 43:19-44:24, 51-10-53:9; Tr. Day 1 (1) 49:4-14; Tr. Day 1 (2) 49:19-50:9; JTX 51-56; JTX 44; JTX 540. Dr. Katz routinely documented, in his laboratory notebook, the

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- names of people that were involved in his work. For example, Dr. Katz included Dr. Llull, Dr. Jeong, Dr. Bashon, Peggy Marcone, Patricia Petrosko, Dr. CD, Oguz, and Chris Gunther in his laboratory notebooks. Day 3 (1) 8:21-9:13, 53:21-54:13, 55:17-56:6, 56:7-57:21, 78:18-79:1; JTX 52:29, 39; JTX 53:47; JTX 55:19, 23.
- Dr. Katz listed Drs. Hedrick and Llull as "informal scientific 34. supervisors/mentors" in a research agreement that required Dr. Katz to have a mentor advisor. JTX 886; Tr. Day 4 (2) at 14:22-15:6, 43:23-44:8.
- 35. In late 1997 to early 1998, Dr. Hedrick wrote a research proposal that set forth some experiments designed to characterize human adipose-derived mesenchymal progenitor and stem cell characterization. JTX 69.
- In April 1998, Drs. Katz, Llull, and Hedrick submitted an Invention Disclosure 36. to UPitt entitled "Adipose (fat)-derived Multipotent Precursor Cells and Uses Thereof." JTX 46. The Invention Disclosure states that isolated stromal cells from human fat tissue "can be induced to develop into fat, bone, cartilage, and muscle tissues given the appropriate culture milieu based on our research results." Id. The Invention Disclosure lists October 1996 as the first date of conception. Id. at P1319.
- The Regenerative Bioengineering and Research ("REBAR") Lab was founded 37. at UCLA in August 1998 by Drs. Benhaim, Lorenz, and Hedrick. JTX 9; JTX 1; JTX 64; JTX 83; Tr. Day 8 (1) at 7:5-8; Tr. Day 8 (2) at 24:2-5. Dr. Hedrick continued to research "the further delineation of the multipotent nature of human lipo-derived cells." JTX 165.
- Some time in 1998, Dr. Katz focused his researched efforts more on "the 38. exploitable potential of liposuctioned fat tissue for transplantation, tissue engineering, and gene therapy applications." Id.
- In March 1999, UPitt filed Provisional Patent Application No. 60/123,711. 39. Pre-trial Conf. Order at 3. The application claims a method of "differentiating

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- adipose-derived stem cells" by "isolating and expanding" cells and then culturing them in media to induce osteogenic (bone), adipogenic (fat), chondrogenic (cartilage), and myogenic (muscle) differentiation. JTX 302. This application lists Drs. Katz, Llull, Futrell, and Hedrick as inventors. The '231 patent claims priority over to the Provisional Patent Application No. 60/123,711 under 35 U.S.C. § 119(e). JTX 59.
- In June 1999, Dr. Zhu joined the REBAR lab. JTX 68; Pre-trial Conf. Order at 40. 3. In late 1999, the UCLA researchers differentiated SVF cells using a variety of media. Tr. Day 6 (1) at 9:8-21. They also identified telomerase enzyme, a stem cell marker, in a heterogeneous population of SVF cells. *Id.* at 9:22-25; JTX 870.
- In October 1999, UPitt filed Provisional Patent Application No. 60/162,462 41. ("the Second Provisional"), listing Drs. Katz, Llull, Futrell, and Hedrick as inventors. JTX 303; Pre-trial Conf. Order at 3. The Second Provisional acknowledged that cloning experiments were ongoing to determine whether adipose-derived stem cells exists in human liposuctioned fat tissue and the similarities of adipose-derived stem cells to bone marrow-derived mesenchymal stem cells. JTX 303 at 41.
- Research at UCLA showed that adipose-derived stem cells are distinct from 42. prior art bone marrow-derived stem cells because they respond differently to induction media. JTX 804; Tr. Day 7 (1) 16:6-17:22.
- In late 1999 and early 2000, Defendants were able to clone single adipose-43. derived cells. JTX 863; JTX 864; JTX 873-875; Tr. Day 7 (2) at 14:6-16:17, 21:21-33:19; see also JTX 812, JTX 813.
- In February 2000, Dr. Hedrick submitted an Invention Disclosure to UCLA for 44. stem cells derived from adipose tissue. JTX 105. He wrote "1997" as the date the invention was "first conceived" and "first successfully tested" and indicated that the work underlying the disclosure began in 1996. JTX 105; Tr. Day 7 (1)

- 78:15-81:7. Also in early 2000, Dr. Hedrick began providing UPitt's patent attorney with information to include in the '231 patent including recipes for the induction medium reported in the examples section of the '231 patent. JTX 801.
- 45. On March 10, 2000, UPitt filed International Patent Application PCT/US00/06232. JTX 59. This application lists all seven of the named inventors of the '231 patent. *Id*.
- 46. On October 29, 2004, UPitt filed the current action to remove Defendants as inventors of the '231 patent. On February 9, 2006, Defendants filed a counterclaim against Plaintiffs to remove Drs. Katz, Llull, and Futrell as inventors of the patent. Dr. Futrell filed an unopposed motion to dismiss himself from the case which the Court granted on June 20, 2006. On February 13, 2007, the Court issued an Order construing disputed claims in the patent. On August 9, 2007, the Court granted Plaintiffs' motion for summary judgment finding that Drs. Katz and Llull are properly named inventors; however, the Court denied summary judgment for Plaintiffs that Drs. Benhaim, Lorenz, and Zhu are not proper inventors of the '231 patent, stating material issues of fact in dispute regarding whether Plaintiffs alone conceived of the invention. The Court also denied Defendants' motion for summary judgment in its entirety. 8/9/07 Order at 3, 17-18.

CONCLUSIONS OF LAW

47. There is a presumption that an individual named as inventor of a patent is correctly named as an inventor of a patent. Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980 (Fed. Cir. 1997). Removal of a named inventor from a patent requires proof by clear and convincing evidence. Cook Biotech. Inc. v. Acell, Inc., 460 F.3d 1365, 1373 (Fed. Cir. 2006); Eli Lilly and Co. v. Aradigm Corp., 376 F.3d 1352, 1358-59 (Fed. Cir. 2004). Plaintiffs must show

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- that they conceived of every claim of the patent and that any contribution by defendants to the conception of each and every claim was insignificant. Id.
- "A joint invention is the product of a collaboration between two or more 48. persons working together to solve the problem addressed ... [p]eople may be joint inventors even though they do not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution, ... [t]he statute does not set forth the minimum quality or quantity of contribution required for joint inventorship." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1227 (Fed. Cir. 1994) (internal citations omitted). 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; see Eli Lilly, 376 F.3d 1352, 1358-59 (Fed. Cir. 2004).
- 49. "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. The obviousness of a claimed feature is irrelevant to the conception determination. *Id.* at 1232.
- "A party must show possession of every feature recited in the count, and that 50. every limitation of the count must have been known to the inventor at the time of the alleged conception." Hitzeman v. Rutter, 243 F.3d 1345, 1354 (Fed. Cir. 2001) (internal citations omitted).

- 51. 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). The inventor need not be the first to appreciate the patentability of the invention. *Id*.
- 52. 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).
- "Conception is a prerequisite to an adequate written description" because "[o]ne cannot describe what one has not conceived." *Falkner v. Inglis*, 448 F.3d 1357, 1367, n.13 (Fed. Cir. 2006).
- 54. 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, 1116-17 (N.D. Cal. 2007).
- 55. 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).
- 56. Contributions relating to aspects of the invention that do not find their way into the defined invention in a patent claim cannot serve as the basis for a claim of co-inventorship. See Eli Lilly, 376 F.3d at 1362 (citing Ethicon, 135 F.3d at 1461-63 for "granting co-inventorship status provided the person 'contributed to the invention defined by' a claim or 'if [the person's] contribution found its way into the defined invention' in a claim.")

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- Conception does not require conclusive physical experiments, scientific proof, 57. and confirmation of operability of the concept or idea in the inventors' minds. Burroughs, 40 F.3d at 1227-28, 1230; In re Jolley, 308 F.3d 1317, 1321 (Fed. Cir. 2002). A suggestion to "evaluate" a "possibility" can be enough to demonstration conception, and no rule 'excludes "research proposals" as evidence of conception.' In re Jolley, 308 F.3d at 1321, 1323. However if experimentation reveals uncertainty that so undermines the specificity of the inventor's idea, then conception is not complete. See Burroughs, 40 F.3d at 1229.
- While reduction to practice is not required for conception, it ordinarily 58. provides "the best evidence that an invention is complete." Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 66 (1998); see Trovan Ltd. v. Sokymat Sa., 299 F.3d 1292, 1309 (Fed. Cir. 2002) ("Gustafson's reduction to practice alone is evidence that Gustafson had a definite and permanent idea of the complete and operative invention.").
- Conception is a mental act, so "courts require corroborating evidence of a 59. contemporaneous disclosure that would enable one skilled in the art to make the invention." Burroughs, 40 F.3d at 1228.
- A court may infer conception of a claim limitation from the fact that artisans in 60. the field would have understood the invention that had been conceived to possess the limitation, even in the absence of contemporaneous documentation expressly reciting the limitations. *Burroughs*, 40 F.3d at 1231-32.
- The purpose of the corroboration requirement is to determine if an inventor's 61. testimony related to actual research or whether it constitutes "litigationinspired fabrication." Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350-51 (Fed. Cir. 2001). "Because documentary or physical evidence is created at the time of conception, ... the risk of litigation-inspired fabrication or exaggeration is eliminated." Id. at 1351; Mahurkar v. C.R. Bard,

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- Inc., 79 F.3d 1572, 1577 (Fed. Cir. 1996). "All of the evidence ... must be considered as a whole." Conception of the entire invention need not be reflected in a single document. Price v. Symsek, 988 F.2d 1188, 1196 (Fed. Cir. 1993).
- 62. 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). Corroboration is not required for physical exhibits as a condition for its serving as evidence of conception. See Mahurkar, 79 F.3d at 1577-78 (the court does not require corroboration since the trier of fact can conclude for itself what documents show, aided by testimony as to what the exhibit would mean to one skilled in the art.)
- "Documentary or physical evidence that is made contemporaneously with the 63. inventive process provides the most reliable proof that the inventor's testimony has been corroborated." Sandt, 264 F.3d at 1350-51.
- The court applies a "rule of reason" analysis to determine whether the 64. inventor's prior conception testimony has been corroborated; it looks at all pertinent evidence so that a sound determination of the credibility of the inventor's story may be reached. See Price, 988 F.3d at 1195; Medichem, 437 F.3d at 1170. "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

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- claim of co-inventorship." Ethicon, 135 F.3d at 1464 (internal citations omitted).
- 65. By April 1997, 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. See Findings of Fact ¶¶ 11-14, 17-21, 31; see also Sandt, 264 F.3d at 1350-51.
- The media and protocols in Dr. Katz's notebooks would enable one skilled in 66. the field to isolate adipose-derived stem cells and differentiate them into each lineage claimed in the '231 patent. See Findings of Fact ¶ 21; see Sandt, 264 F.3d at 1350-51; *Burroughs*, 40 F.3d at 1223, 1228.
- Also, by April 1997, Drs. Katz and Llull had the definite and permanent idea 67. that the above noted cells could be passaged fifteen 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 1231-32; see Findings of Fact ¶¶ 13, 15, 16.
- 68. 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. See Findings of Fact ¶¶ 21, 22. 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. See Findings of Fact ¶ 23; see also Ethicon, 135 F.3d at 1460.

- 69. 35 USC Section 102 (g)(2) provides that "[a] person shall be entitled to a patent unless ... before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102 (g)(2). Section 102 (g) pertains to "an interference" where the court must determine "priority of invention." See id. The current case involves a suit to correct misjoinder of a named inventor under 35 U.S.C. Section 256 and not "interference" to determine priority of invention. In addition, Defendants did not preserve the issue of abandonment for trial. See Pre-trial Conf. Order.
- 70. Additionally, before Dr. Hedrick's arrival at UPitt, Drs. Katz and Llull had the firm and definite idea that their cells could be cultured in substantially homogeneous populations. See Findings of Fact ¶¶ 24-29, 31.
- Drs. Katz and Llull had the firm and definite idea that the adipose-derived stem 71. cells were human, could be genetically modified, secreted hormones, and contained cell-surface bound intracellular signaling moiety by April 1997. See Findings of Fact ¶ 30. 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 1231-32.
- 72. 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 Findings of Fact ¶¶ 5, 6, 8-17, 19-22, 27, 28, 31; see Amgen, Inc., 927 F.2d at 1206; see also Price, 988 F.2d at 1195. 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 is also immaterial whether they appreciated the legal patentability or novelty of their invention. See Dow, 267 F.3d at 1341.
- Defendants' research after conception confirmed the operability of the 73. invention and included recipes for the induction medium reported in the

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examples section of the '231 patent. See Findings of Fact $\P\P$ 40, 42-44. 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 (internal citation omitted).

- Clear and convincing evidence demonstrates that Drs. Katz and Llull 74. completed conception of all of the claims of the '231 patent at UPitt prior to Dr. Hedrick's arrival at UPitt and/or prior to any of the Defendants' work at UCLA. See Findings of Fact ¶¶ 5-6, 8-22, 24-28, 30-32.
- 75. 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. See Findings of Fact ¶ 23, 40, 42-44, 56.
- 76. Clear and convincing evidence demonstrates that Drs. Katz and Llull are the sole inventors of the claims of the '231 patent.

CONCLUSION

The Court finds that Drs. Katz and Llull are the sole inventors of the '231 patent and that Drs. Hedrick, Benhaim, Lorenz, and Zhu are not inventors. Accordingly, pursuant to 25 U.S.C. § 256, the U.S. Patent & Trademark Office shall correct the inventorship of the '231 patent to reflect that the correct inventors are Adam J. Katz and Ramon Llull.

To the extent that any findings of fact constitute conclusions of law, they are adopted as such, and to the extent that the conclusions of law constitute findings of fact, they are adopted as such.

IT IS SO ORDERED.

UNITED STATES DISTRICT JUDGE