ASPEN PUBLISHERS

OCTOBER 2008

DEVOTED TO LEADERS IN THE INTELLECTUAL PROPERTY AND ENTERTAINMENT COMMUNITY

VOLUME 28 NUMBER 9

THE Licensing Journal

Edited by the Law Firm of Grimes & Battersby

Wolters Kluwer
Law & Business

Licensing Markets

Biotechnology and Pharmaceutical Licensing

Ernest V. Linek

Licensee Due Diligence—Who Owns the Patent?

One of the first issues to be considered in a patent license situation, by both the licensee and the licensor is: Who owns the patent?

The named inventors on a US patent are presumed to be the owners under the patent laws of the United States. The inventors can, and often do, assign their rights to an assignee—usually based on a pre-existing agreement between the parties. When I was first hired as a chemist, I signed an agreement that assigned all of my inventions to my employer, and I also agreed to sign any additional papers required to make such assignments effective. Employment agreements of this type are routine. I was hired to make inventions, and the inventions were owned by my employer. Inventorship and ownership are thus issues that must always be considered together as part of the due diligence in a licensing situation.

Patent ownership in the United States is subject to the statutory requirements of Title 35, United States Code, Section 261. As stated therein, "patents shall have the attributes of personal property." Assignments of patent applications and patents, or interests therein, must be made by an instrument in writing.

Under the patent laws of the United States [35 U.S.C. 262], every owner of a patent is free to make, use, offer to sell, or sell the patented invention in the United States, without the consent of, and without accounting to any of the other owners—absent an agreement to the contrary.

In other words, under the patent laws of the United States, two or more owners of a patent may separately grant licenses to different parties, each of whom may then practice the invention, without fear of litigation from the non-license granting owner. But what happens if the inventorship on a patent changes? What happens if certain inventors are found to be non-inventors?

That is what happened in 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*, one of the patent assignees, UPitt, filed suit against some of the named inventors, seeking to correct the inventorship of a patent jointly owned with the Regents of the University of California, specifically by deleting all of the named UCal inventors. The patent in question is U.S. Patent No. 6,777,231 (the '231 patent). The '231 patent has 10 claims, reproduced here:

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 homogeneous 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.

Inventorship

To properly be named an inventor under the patent laws of the United States, a person must have made an inventive contribution to the conception of one or more of these claims. An inventive contribution requires a "conception" of

the invention, that is, the mental act of conceptualizing the idea. If the idea is "complete," that is all that is required. The act of inventing has been concluded. However, if the idea is not complete, but instead requires additional work for complete conceptualization of the idea, or it needs a reduction to practice that requires more than simple routine work, then the inventive act is not completed until it is finalized.

As shown by the claims, the '231 patent relates to adipose-derived stem cells. When granted, the '231 patent lists seven inventors. Adam J. Katz (UPitt), Ramon Llull (UPitt), J. William Futrell (UPitt), Marc H. Hedrick (UCal), Prosper Benhaim (UCal), Hermann Peter Lorenz (UCal), and Min Zhu (UCal).

Under the patent laws of the United States, 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)].

To be successful in this case as plaintiff, UPitt was required to show that the UPitt inventors conceived of every claim of the patent and that any contributions made by the UCal inventor defendants to the conception of each and every claim were insignificant.

A joint invention is the product of a collaboration between two or more 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)].

Burroughs involved the inventorship of patents that claimed the use of AZT to treat human patients with HIV/AIDS. The Burroughs inventors claimed to have conceived of AZT as a treatment for HIV (a human retrovirus) based solely on the finding that the drug was effective against certain murine (mouse) retroviruses. [*Id.* at 1225-26; **Note:** At my former law firm I worked with the patent attorney who wrote the Burroughs Wellcome patents on the use of AZT (Mr. Donald Brown), and assisted in the inventorship review when the NIH made its claims against the patents].

The defendants argued that scientists at the National Institutes of Health (NIH), whose later research and experiments actually proved that AZT was effective in the claimed treatment of HIV in humans, were improperly omitted as inventors [*Id.* at 1227–1228]. Specifically, the defendants contended that Burroughs' preliminary results could not have supported a reasonable belief that AZT would treat HIV in humans. On that basis, the defendants argued that "when the invention deals with uncertain or experimental disciplines, where the inventor cannot reasonably believe an idea will be operable until some result supports that conclusion," the absence of experimental proof precludes a finding that conception has occurred [*Id.* at 1228]. The defendants thus contended that in order to satisfy the "definite and permanent idea" test for conception, an inventor must possess a "reasonable expectation" that the invention will work for its intended purpose, and, therefore, only the later human tests performed at NIH were sufficient to establish conception [*Id.*]. In the absence of such experiments and proof, the defendants argued, the inventor had "only a hope or an expectation" and had not yet conceived of the invention in sufficiently definite and permanent form to warrant a patent [*Id*].

The Federal Circuit's response could not have been clearer: "this is not the law" [*Id*]. The court rejected the defendants' contentions, holding that the predictive value of the murine tests, and the reasonableness of the conclusion that Burroughs' scientists drew from them, had no bearing on the specificity and definiteness of the idea that AZT would effectively treat HIV:

> Regardless of the predictive value of the murine tests, however, the record shows that soon after those tests, the inventors determined, for whatever reason, to use AZT as a treatment for AIDS.

Ernest V. Linek is a partner in the Boston, MA office of Banner & Witcoff, LLP.

Reprinted from *The Licensing Journal* October 2008, Volume 28, Number 9, pages 27-28, with permission from Aspen Publishers, Inc., Wolters Kluwer Law & Business, New York, NY, 1-800-638-8437, www.aspenpublishers.com