KEVIN J. MCGOUGH

The inventorship lessons of *Burroughs Wellcome*

This summer the U.S. District Court for the Eastern District of North Carolina upheld the validity and enforceability of Burroughs Wellcome's (BW, Greenville, NC) patents on the use of azidothymidine (AZT) to treat persons infected with HIV. Barr Laboratories (Panoma, NY) and Novopharm (Schaumberg, IL) sought to market generic versions of BW's AZT drug Retrovir prior to the expiration of BW's patents. Barr and Novopharm maintained before the Food and Drug Administration (FDA, Bethesda, MD) and the federal district court that they should be allowed to do so, because BW's patents were allegedly invalid for failure to name the correct inventors.

According to Barr and Novopharm, BW should have named two National Institutes of Health (NIH, Bethesda, MD) scientists—Samuel Broder and Hiroaki Mitsuya—as joint inventors, together with the named BW inventors. At the instruction of BW scientists, and without knowing the identity of the compound they were using, Broder and Mitsuya were the first to test AZT against live HIV and report its positive activity against replication of HIV.

To understand why the *Burroughs Wellcome* Court rejected Barr's and Novopharm's assertions and upheld the BW patents, it is helpful to first consider the basic principles of patent inventorship in the biotechnological and pharmaceutical arts (see also "The Invention Equation," this issue). *Burroughs Wellcome*'s application of these principles serves as a useful guide in assessing whether someone should be named as an inventor on a biotechnology patent.

There are two components of inventorship under U.S. patent law: conception and reduction to practice. Conception has been defined by the courts to mean the formation in the mind of the inventor of a definite and permanent idea of the complete and operable invention. In other words, once an invention has been conceived, one of ordinary skill in the art can make it or use it without undue experimentation. Importantly, to be considered as an inventor, one must have contributed to the conception of the invention.

The second component of inventorship is known as reduction to practice. Reduction to practice means that the invention has been shown to work for its intended purpose. The filing of a patent application has been held to constitute a constructive reduction to practice.

When BW scientists learned in mid-1984 that AIDS was caused by a retrovirus, they began to screen antiviral compounds against two murine retroviruses, the Friend leukemia virus and the Harvey sarcoma virus. On October 29, 1984, AZT was selected by BW for testing in the murine screens, and it exhibited a significant activity at low concentrations. Shortly thereafter, BW decided to prepare a patent application covering the use of AZT as an AIDS therapy.

On February 4, 1985, BW sent a sample of AZT under the code name "compound S" to Broder at the NIH and suggested that he test it against HIV in human cells at four different concentrations. Subsequently, BW completed a draft patent application that included the AZT dosages ultimately approved by the FDA.

Mitsuya, Broder's coworker, tested "compound S" in mid-February 1985, after BW's draft patent application had been prepared, and found it to be active against HIV. These results were reported to BW by Broder on February 20, 1985, and BW filed a U.K. patent application on the use of AZT to treat persons infected with HIV on March 16, 1985.

On these facts, the *Burroughs Wellcome* Court entered judgment in favor of BW without sending the case to the jury. The heart of the court's decision was its conclusion that the BW scientists conceived of the treatment of AIDS using AZT when they defined and preserved their idea of the drug's utility for this therapy, most notably in their draft patent application. According to the court, this standard of conception is wholly subjective. Indeed, the BW scientists did not need to predict accurately that AZT would in fact work. Further, the NIH scientists played no role in the conception of the invention and therefore could not have been properly named as inventors. Instead, according to the court, the NIH scientists were merely a "pair of hands" working for BW.

Burroughs Wellcome is consistent with established case law on chemical and pharmaceutical inventorship. It is settled that the conception of a compound or a method of using a compound is complete prior to routine experimentation that establishes a particular utility.

An important lesson to draw from *Burroughs Wellcome* is that the conception of a biotechnology invention should be memorialized as quickly and in as broad of terms as possible. As in *Burroughs Wellcome*, a draft patent application could be used for this purpose, one incorporating the inventor's best current understanding of how the invention can be reduced to practice, including dosage ranges, pharmaceutical composition, requisite chemical synthesis, or recombinant techniques. ///

Kevin J. McGough of Bronxville, NY, is a patent attorney whose practice involves pharmaceutical and health-care matters.