Ruling due in Cistron vs. Immunex trial

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NEW YORK—The stage is being set for one of the biotechnology industry's most significant trials, as Judge William L. Dwyer of Seattle's Federal District Court considers motions for dismissal on behalf of Immunex Corporation (Seattle, WA) in the case of Cistron (Pine Brook, NJ) vs. Immunex. Cistron is suing Immunex over the patent rights to interleukin-1β (IL-1β), a powerful immune system hormone. In addition to the rights to Immunex's IL-1β patent, Cistron is seeking actual and punitive damages that may amount to as much as $160 million.

At the heart of the matter is Cistron's discovery, several years ago, that Immunex's patent covering IL-1β contains seven nucleotide sequence errors that exactly match seven errors that were present in Cistron's IL-1β sequence when it was submitted for peer review and publication in the journal *Nature*. *Nature* declined to publish the manuscript, basing its decision in part on an unfavorable review by Immunex's Vice President for Research, Steven Gillis. Among other charges, Cistron alleges that Immunex scientists improperly obtained the sequence from Gillis, and used it in their own work, including the filing of Immunex's patent.

Cistron's claims for damages stem from their contention that top level Immunex executives conspired to defraud the U.S. Patent Office (Washington, D.C.), the public, and Cistron's potential investors. Cistron, which at one point entered bankruptcy proceedings, accuses Immunex of having engaged in lucrative research contracts with other companies, in part by fraudulently claiming that Cistron had not cloned IL-1β, and that Immunex had independently done so.

The motion to dismiss is based on Immunex's contention that the statute of limitations had expired before Cistron brought its case, and on the premise that Cistron's IL-1β sequence was made public at a scientific conference, which made it freely available for Immunex to use.

If Immunex's motion to dismiss is denied, the case will move to a trial date now scheduled for April, 1996. Cistron has asked for a jury trial, so that lay jurists will be asked to render a verdict based on interpretation of the DNA evidence. With such a large sum of money at stake, as well as the rights to a primary immune and inflammatory stimulant, the outcome of the case may have profound effects on the litigants. Loss would be an extreme financial blow to Immunex, and victory would immediately transform Cistron from a "have-not" biotechnology company to a substantially endowed corporation.

—Susan Hassler

Back to basics for gene therapy and RAC

WASHINGTON, D.C.—Two reports, presented in December to U.S. National Institutes of Health (NIH, Bethesda, MD) Director Harold Varmus, provide a mixed but unflattering picture of progress in gene therapy research. The one sharply criticizes hastily conducted and poorly designed clinical trials, recommending a renewed emphasis on basic research instead of further additions to the schemes for several dozen diseases now being tested in several hundred patients. The other report recommends that the NIH Recombinant DNA Advisory Committee (RAC), which oversees much of this clinical research, should narrow its focus and further streamline its review activities instead of going out of business.

Criticism of RAC from industry and AIDS activists, many of whom wanted RAC to shut down, prompted Varmus to seek an outside evaluation of the committee early in 1995. Critics argued that RAC review of gene therapy clinical proposals duplicated those conducted by the Food and Drug Administration (FDA, Rockville, MD). Moreover, they complained, RAC was delaying the development of novel, potentially life-saving approaches for treating AIDS, cancer, and a variety of hereditary disorders.

Initially, Varmus established a single committee, chaired by virologist Inder Verma of the Salk Institute (San Diego, CA), to review RAC's performance and to look more broadly at gene therapy research. Subsequently, Varmus decided that this second task needed a separate review effort. So he formed another committee, co-chaired by Stuart Orkin of Harvard Medical School (Boston, MA) and Arno Motulsky of the University of Washington (Seattle, WA), to assess gene therapy research and to advise NIH on marshalling federal resources for this area.

Even though the prospects for this research "are great, clinical efficacy has not been definitively demonstrated," concluded Orkin, Motulsky, and other panel members. "Significant problems remain in all basic aspects of gene therapy." Hence, the panel members call for a "greater focus on basic research," not only on vector development and stem cell biology (the bullets and targets for gene therapy), but also on other fundamental problems, including disease pathogenesis and animal models of disease.