



Federal Judge Enters Final Post-Judgment Orders In Favor Of Integra Lifesciences -- Merck KGaA Held To Infringe Patents

PLAINSBORO, N.J.--(BUSINESS WIRE)--Oct. 17, 2001--Integra LifeSciences Holdings Corporation (NASDAQ:IART) announced today that the United States District Court for the Southern District of California entered orders in favor of the plaintiffs and against Merck KGaA on the final post-judgment motions in the case of Integra LifeSciences I Ltd. and The Burnham Institute v. Merck KGaA.

The Court denied Merck KGaA's motions for judgment as a matter of law and for a new trial, in each case regarding infringement, invalidity, and damages.

The Court's orders signal the beginning of the appellate process for the \$16,350,000 judgment (including pre-judgment interest) entered September 29, 2000, in favor of plaintiffs and against Merck KGaA. Post-judgment interest continues to accrue at the rate of approximately \$20,000 per week. Integra has not recorded any gain in connection with this favorable judgment.

The lawsuit, which was filed in 1996, alleged that Merck KGaA and a non-profit research institution under contract from Merck KGaA had infringed various United States patents held by The Burnham Institute of San Diego that have been licensed to Integra.

Those patents include No. 4,792,525, No. 4,879,237, No. 5,695,997, and No. 4,789,734, each in various ways relating to technology involving peptides containing an arginine-glycine-aspartic acid (RGD) sequence or related cell surface receptors.

Compounds containing the RGD sequence promote or inhibit cell adhesion by binding receptors called integrins found on the surface of almost every cell in the body.

Merck KGaA entered Phase I/II clinical testing with its RGD compound (designated EMD 121974) for the treatment of cancer in November of 1999. The goal of this trial is to starve the cancer by inhibiting angiogenesis, which is the growth of new blood vessels into the tumor. It is hoped that this approach will be applicable to many types of cancers.

The damages reflect the amount that the jury determined that Merck KGaA would have been willing to pay in a hypothetical negotiation in 1995 to avoid the impediments of the plaintiffs' patents. In effect, the damages awarded under the judgment compensate the plaintiffs for milestone and other payments that the plaintiffs would have received from Merck KGaA had Merck KGaA taken a license from the plaintiffs.

The damages do not purport to include royalties based upon future sales of Merck KGaA's compound. The Court therefore left open the possibility that Integra could recover additional payments in the event that Merck KGaA's RGD compound receives FDA approval and begins sales in the United States.

The Court also left open the possibility that Merck KGaA could be enjoined from any future sales in the event it successfully obtains FDA approval.

In addition to the patents that were the subject of the litigation, Integra has licensed additional RGD-related patent protection from The Burnham Institute since the close of the pleadings in the Merck litigation.

Those patents include U.S. Patent Nos. 6,020,460; 5,985,827; 5,981,468; 5,906,975; 5,880,092; 5,994,501; 5,827,821 and 5,916,875 and European Patent No. EP 0 394 326 B1, each in various ways relating to technology involving compounds containing an RGD sequence.

All of these patents (including the patents that are the subject of the litigation) derive from the pioneering work of Erkki Ruoslahti, M.D., Ph.D., President and CEO of The Burnham Institute (formerly the La Jolla Cancer Research Foundation), and Michael D. Pierschbacher, Ph.D., Senior Vice President and Director of Integra's Corporate Research Center in San Diego.

"We are obviously pleased that the Court has ruled in our favor on all six post-judgment motions and confirmed last year's judgment," said John B. Henneman, III, Integra's Chief Administrative Officer. "The patents in the case, plus the more recent patents that were not included in the case, are of central importance to most, if not all, uses of the RGD sequence. In addition to their application for controlling angiogenesis, we believe that these patents describe compounds that include non-naturally occurring small peptides with other clinical applications, including the inhibition of the platelet aggregation that can cause

thrombosis."

Pharmaceutical companies or research organizations interested in discussing a license to the Burnham/Integra patents should contact Mr. Henneman.

Integra expects that Merck KGaA will appeal various decisions of the Court. Integra may appeal the denial of exemplary damages, in light of the jury's determination that Merck KGaA's infringement was willful.

The plaintiffs were represented in the case by Campbell & Flores LLP of San Diego.

Integra LifeSciences Holdings Corporation develops, manufactures and markets medical devices, implants and biomaterials primarily used in the treatment of cranial and spinal disorders, soft tissue repair and orthopedics. Integra is a leader in applying the principles of biotechnology to medical devices that improve patients' quality of life.

The Company has its corporate headquarters in Plainsboro, New Jersey and has approximately 585 permanent employees.

Statements made in this press release may be forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from predicted results. Forward-looking factors that may be discussed include, but are not limited to, the results of litigation and related appeals and the value of intellectual property. In addition, the economic, competitive, governmental, technological and other factors identified under the heading "Risk Factors" included in the Business section of Integra's Annual Report on Form 10-K/A for the year ended December 31, 2000 and information contained in subsequent filings with the Securities and Exchange Commission could affect actual results.

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