

## High Court Expands Patent Infringement Exemption

The United States Supreme Court has unanimously adopted a broad interpretation of a statutory defense to patent infringement claims. This expanded defense will enable pharmaceutical researchers to use patented compounds or inventions, without a license, to generate data that may eventually be submitted to the FDA. In *Merck KgaA v. Integra Lifesciences I Ltd.*, \_\_\_ U.S. \_\_\_, 125 S.Ct. 2372 (June 13, 2005), the Court held that the infringement defense can apply to preclinical trials as well as clinical trials and to a fairly broad category of pharmaceutical research. The decision is seen as a loss for certain patent holders and a win for universities and others that conduct preclinical and clinical research into new pharmaceutical therapies.

Merck KgaA, which is not affiliated with the pharmaceutical giant Merck & Co., conducted research using certain RGB peptides that act as tumor inhibitors. Integra Lifesciences I Ltd. holds five patents on RGB peptides. Integra offered a license to Merck, which was declined. Integra then sued for infringement. Merck defended by arguing that its use of the peptides fell within the safe harbor provided by Section 202 of the Drug Price Competition and Patent Term Restoration Act of 1984. That section provides an infringement defense for users of patented inventions "solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs." The jury rejected the defense and returned a verdict of \$15 million against Merck. The Court of Appeals affirmed the trial court's verdict, holding that the defense did not apply to "general biomedical research to identify new pharmaceutical compounds."

The Supreme Court, in an opinion written by Justice Scalia, unanimously reversed the lower courts. The Supreme Court held that the stage of research is immaterial, concluding that the exemption "extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the" Food, Drug and Cosmetic Act. The Court also noted that scientific testing is a trial and error process and research that did not actually result in a FDA filing can also be entitled to the exemption. The Court held the researcher only needs a "reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and use the compound in research that, if successful, would be appropriate in include in a submission to the FDA."

Universities with large pharmaceutical patent holdings had sided with Integra. However, most universities have applauded the Supreme Court's decision. One unanswered question is the effect the *Merck* decision may have outside the pharmaceutical arena. Universities were disappointed with an earlier Federal Circuit Court of Appeals decision in *Madry v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002), which held that the common law experimental use defense to a patent infringement claim applied only to uses "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." The *Merck* case provides some basis for optimism in the higher education community that the Supreme Court may, some day, overrule *Madry* and expand the scope of the experimental use defense.