

The Value of Research Tool Patents

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Recent legal controversies have led to uncertainty regarding the value of research tools and patents covering them. In particular, the U.S. Supreme Court's *Merck v. Integra* decision has broadened the safe harbor exemption for patented inventions used in drug testing, but it failed to leave a clear view of just how far back into the research and development process the exemption extends. The exemption was formerly seen as limited to the clinical studies that directly generate data for submission to the U.S. Food and Drug Administration (FDA). But now, owners and licensees of research tool patents are asking themselves what their patents are worth in the new legal landscape.

What exactly is a research tool? A narrow view would limit research tools to instrumentation, assay reagents, screening libraries, basic assay methods (e.g., PCR), computer software, and similar materials that are broadly applicable to any scientific research. A broader view would also encompass drug targets (e.g., transgenic animals, cells, receptors, enzymes, genes), candidate drugs, and possibly even patented therapeutic or diagnostic agents, whose use might be part of the discovery process for a new drug or diagnostic agent. The real key to whether a substance or a method is a research tool is how it is used, namely, whether it is used in research. Adopting a narrower definition of research tools is generally not useful, because the same object can be either a research tool or not, depending on how it is used. For example, an antibody can be used as a therapeutic drug (not a research tool), or it can be a component of an assay kit used in the earliest stages of drug research (clearly a research tool).

In certain limited circumstances, the use of patented technology in research can fall within the so-called common law research exemption, under which an otherwise infringing use of a patented composition, device, or method is allowed. The research exemption traces its roots back through nearly 200 years of U.S. court decisions, and it was recently refocused in *Madey v. Duke University*. In *Madey*, the Court of Appeals for the Federal Circuit held that the exemption is limited to the use of a patent for philosophical or scientific inquiry, and made clear that research may not be immune from patent infringement if it has "the slightest commercial implication" or if it furthers the business objectives of the entity using the technology. *Madey* thereby narrowed the research exemption and made clear that research with even minimal commercial implication, including research during the early stages of drug development, may not be eligible for the long-established infringement exemption. Thus, *Madey* has strengthened research tool patents.

Following *Madey*, the U.S. Supreme Court in *Integra v. Merck* evaluated the scope of another statute-based research exemption. In that case, Merck had used Integra's patented RGD peptides during pre-clinical work, while screening a handful of compounds (cyclic RGD peptides) for their ability to inhibit tumor growth. The screened compounds included the one which later was selected for clinical trials. It was generally accepted that the use of the RGD peptides during *clinical* work for FDA approval was exempt from infringement under the statutory safe harbor of 35 U.S.C. § 271(e)(1), which exempts otherwise infringing activities from liability if those activities are "solely for uses reasonably related to development and submission of information [to the FDA for drug approval]". The issue was whether the infringement of a patent during *pre-clinical* (pre-IND) work also qualifies for the safe harbor

