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Legal Alert:

Patent Licensing Requirements under *Madey v. Duke University*

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Several recent cases have clarified the requirements for university research patent licensing. The recent Federal Circuit Court opinion in *Madey v. Duke Univ.*[1] states that no *per se* university experimental use exemption from patent infringement exists. The Court held that regardless of whether a particular institution is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strict philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.[2] According to the Court, a university's legitimate business is not only to educate and enlighten students and faculty, but also to increase the status of the institution and lure research grants, students and faculty.

This decision results in greater predictability for the protection of patented inventions, which so frequently require large financial investments to develop. Just as a university may license out the patented fruits of its own research efforts for financial gain, so too it must pay to license in the patented technology of others that its researchers choose to practice. The Supreme Court reviewed the *Amicus curiae* brief filed by the U.S. Solicitor General in denying the petition for *certioriari* in *Madey* on June 27, 2003, noting that under the Federal Circuit's decision, research institutions are neither automatically entitled to, nor automatically ineligible for, the experimental use defense.[3] Thus, to determine whether the experimental use exemption applies, the courts must consider not simply the legitimate business of the alleged infringer, but the specific uses to which the patented inventions at issue were put.[4] The courts may look to whether the funding grant proposal described an intended commercial use, or whether the infringing research resulted in the filing of additional new patents. As a practical matter, due to most research funding requirements for development of commercial applications for a technology, such as for federal funding under the Bayh-Dole Act,[5] the vast majority of university conducted research will not be exempt from infringement liability as an experimental use.

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[1] *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied* 156 L.Ed.2d 656 (2003).
[2] *Id.*
[3] *See* Brief For The United States as Amicus curiae at 6, *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002)(No. 02-1007) [hereafter U.S. Solicitor General's Brief].
[4] *Id.*
[5] 35 U.S.C. §200 *et seq.*

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Other recent cases, including the June 6, 2003 case of *Integra v. Merck*,[6] have also indicated that the practice of inventions claimed in life sciences research tool patents (e.g., drug screening or cloning techniques) will not avoid infringement under the safe harbor provisions of FDA-related research.[7] Therefore, it is incumbent upon university researchers to address issues of potential patent infringement and licensing requirements with the staff of the university technology licensing office as early as possible to avoid punitive fees and the disruption of ongoing research.

[6] *Integra v. Merck*, Appeal No. 02-1052 LEXIS 11335 (Fed. Cir. June 6, 2003); see also *Infigen v. ACT*, 65 F.Supp.2d 967 (W.D. WI 1999).
[7] 1984 Hatch-Waxman Act, 35 U.S.C. §271(e)(1).