

Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002)
(United States Court of Appeals for the Federal Circuit, October 3, 2002)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The Court of Appeals for the Federal Circuit interpreted the US experimental use exception in a very restrictive way. Regardless of whether a particular institution or entity is engaged in an endeavour 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 strictly philosophical inquiry, the act does not qualify for the experimental use defense.

The facts

Beginning from 1989, John M. J. Madey served for almost a decade as director of the free electron laser lab of Duke University. The lab contained equipment that utilises two of Madey's patents. Madey resigned from his position following a management dispute. Duke, however, continued to operate the equipment in the lab. Madey then sued Duke for patent infringement. Duke relied on the experimental use exception – a common law exception recognised in the United State permitting the use of patented invention solely for research, academic or experimental purposes.

The United States District Court for the Middle District of North Carolina noted the exception should not be construed so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes. It also ruled that to establish infringement, it is Madey who must establish that Duke has not used the equipment at issue solely for an experimental or other non-profit purpose. Madey argued that Duke is in the business of obtaining grants and developing possible commercial applications for the fruits of its academic research. The district court rejected Madey's argument, relying on a statement in the preamble of the Duke patent policy which stated that Duke was dedicated to teaching, research, and the expansion of knowledge and does not undertake research or development work principally for the purpose of developing patents and commercial applications. Thus, Madey did not meet his burden of proof to create a genuine issue of material fact. Madey appealed to the Court of Appeals for the Federal Circuit (CAFC).

In his appeal Madey, first, claimed that the district court improperly shifted the burden to him to prove that Duke's use was not experimental. Second, that the district court applied an overly broad version of the very narrow experimental use defense inconsistent with the precedent. Third that the supporting evidence relied on by the district court was overly general and not indicative of the specific propositions and findings required by the experimental use defense. The CAFC agreed with all the three contentions of Madey.

The legal issues

According to the CAFC, the district court folded the experimental use defense into the baseline assessment of patent infringement. The district court erroneously required Madey to show as a part of his initial claim that Duke's use was not experimental. But the experimental use defense, if available at all, must be established by Duke.

The district court's formulations of the experimental use defense by exempting uses that "were solely for research, academic, or experimental purposes," and the defense as use that "is made for experimental, non-profit purposes only" are too broad. In two previous cases¹ the CAFC established that the experimental use defense is very narrow and strictly limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Further, use does not qualify for the experimental use defense when it is undertaken in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes".

The CAFC ruled that the precedent clearly does not immunize use that is in any way commercial in nature. Similarly, the precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve to increase the status of the institution and lure lucrative research grants, students and faculty. In short, regardless of whether a particular institution or entity is engaged in an endeavour 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 strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

Moreover, the profit or non-profit status of the user is not determinative. In the present case, the correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

¹ *Embrex v. Service Engineering Corp* (216 F.3d 1343, 1349 (Fed. Cir. 2000)) and *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

Points of Significance

1. Universities are encouraged to patent and commercialize the results of their research. This blurs the distinction between scientific and commercial research. Added to that, the interpretation of the experimental use by the CAFC excluding research that furthers the "legitimate business" of universities, even where not commercial, has the effect of practically eliminating the exception.
2. The US approach to the experimental use exception is rather the exception than the rule. Other countries apply a different test, such as commercial vs. non-commercial purpose, or whether the research is intended to yield new knowledge about the invention, regardless of the commercial or non-commercial purpose (e.g. Germany's Federal Court of Justice in *Clinical Trials*²). Courts in the United Kingdom admit commercial research on the patented substance to the extent that commercial gains are not the preponderant objective.³ Switzerland further distinguishes research 'on' the patent – when the research concerns the subject matter of the patent – from research 'with' the patent – when the research concerns the use of research tool patents in experimentation. In both cases, experimental use is justified, whether for commercial or non-commercial purposes, except that the patent owner should be compensated in case of research 'with' the patent.⁴

Key words: Experimental use exception; research exception.

Link: <https://cyber.harvard.edu/people/tfisher/2002Madededit.html>

² German Federal Court of Justice, *Klinische Versuche* (Clinical Trials) I [1997] RPC 623, first page available at <http://rpc.oxfordjournals.org/content/114/15/623.full.pdf+html>

³ High Court of Justice, Patent Court, *CoreValve Inc v Edwards Lifesciences AG & Anor*, available as a summary in this database.

⁴ See UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries. A Reference Guide*, 2011, pp. 104-106, with references to Germany, Switzerland and the UK. Available at https://unctad.org/system/files/official-document/diaepcb2009d19_en.pdf