The Research Exemption in the United States*

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Research Exemption

- A party w/o license from patent owner may experiment with patented technology w/o being liable for infringement damages or subject to an injunction
- “Promoting the Progress of . . . the Useful Arts” – US Constitution (Art 1, sec 8, cl 8)
- Similar to “fair use” under US copyright law, as codified in 17 USC 107 (1976). See leg. history of FDA exemption in 35 USC 271(e)(1)

History of the Research Exemption

- No statute, only case law – common law exemption
- Justice Story in Whittemore v. Cutter (1813) – only philosophical inquiry permitted – research?
- Highest patent court (CAFC) has narrowly interpreted exemption in 4 cases
- Roche v Bolar (1984) – bio-equivalency testing not exempt; overruled by 35 USC 271(e)(1)
- Embrex v. Service Engineering (2000)– designing around actionable; Rader concurring opinion - experimental defense is “de minimis” use and would not apply if any commercial value

History (cont'd)

- Duke University v. Madey (2002) – no exemption for Duke using its professor's patented laser gun
- Merck v. Integra (2005) – SCt reversed and found safe harbor covers pre-clinical testing of drugs under 35 USC 271(e)(1); Newman CAFC dissent – "research on vs. research with" test

Statutory Proposals

- PVPA of 1970 has general research exemption – 7 USC 2544
- HR 4970 (1988) had criteria for exemption; passed the House only
- Section 402 of HR 5598 (1990) to exclude use solely for research unless primary purpose of invention is research; did not pass
- AIPLA 2004 proposal - OK if to determine the validity and scope of the patent and understand features of the patent
- Universities have no formal position on exemption; many license their research tools
- Art 30 of TRIPS – countries may provide limited exception to exclusivity if does not “unreasonably prejudice” patent owners
- No current legislative proposal although several patent reform bills