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SUPREME COURT BROADENS RESEARCH EXEMPTION

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On June 13, 2005, the United States Supreme Court ruled unanimously in *Merck KGaA v. Integra Lifesciences I, Ltd.*, giving a broad construction to the research exemption provided by 35 U.S.C. § 271(e)(1), and overturning the Federal Circuit Court of Appeals' narrower interpretation of the language. § 271(e)(1) reads, "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . 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 or veterinary biological products."

At issue in *Merck* was the company's funding of cancer research which involved experimentation on RGD peptides as angiogenesis inhibitors. These RGD peptides are the subject of patents owned by Integra Lifesciences I, Ltd., and the Burnham Institute. In particular, the Court examined the issue of whether preclinical research that identifies the best drug candidate for future FDA testing is covered by § 271(e)(1) or constitutes patent infringement. The Court held that the "exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA."

The Court disregarded Integra's arguments that patented compounds could only be used to submit preclinical data related to the safety of a drug in

humans, that testing on patented compounds must comply with the FDA's good laboratory practice regulations, that the research exemption does not reach experimentation on drugs that are not submitted to the FDA, and that experiments that are not later included in a submission of information are infringing. Recognizing that drug development is a complex, multistage process, and that the language of § 271(e)(1) calls for exemption for "reasonably related" uses rather than solely successful uses, the Court was unwilling to limit the applicability of the research exemption based on the stage where the patented compound is used. The Court explained, "At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law.'" The Federal Circuit, by contrast, had given a strict interpretation to the statutory language, encouraging the application of the exemption to research submitted directly to the FDA, and focusing on the use of the exemption to allow for expedited approval of generic drugs rather than to apply to experimentation at all stages of new drug development. In light of the Supreme Court's remand, the Federal Circuit has called for further briefing in *Merck*, "with particular attention paid to the Supreme Court decision."

Notably absent from the Court's opinion was a decision on the application of the research exemption to patented research tools. In a footnote, the Court explained that the Federal Circuit's treatment of the research tool issue was unnecessary and declined to rule, "Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process." This portion of the opinion provided some relief to patent holders and academic institutions. For example, life sciences company Invitrogen Corporation, which had taken part in an amicus brief arguing against the application of § 271(e)(1) to patented research tools, issued a statement that the ruling "will not have a material effect on Invitrogen's business."

For large pharmaceutical companies, however, this ruling is a clear victory, providing some breathing room in their research and testing procedures and insulation from accusations of patent infringement. While drug manufacturers and scientists are still prohibited from using patented compounds in general research that bears no relationship to FDA submissions, the Supreme Court has carved out the ability for researchers to use patented compounds earlier in the drug development process

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