

INTEGRA V. MERCK: EXPERIMENTAL USE SAFE HARBOR UNDER 35 U.S.C. §271(e)(1)

In a unanimous opinion, the Supreme Court recently expanded the patent infringement safe harbor under 35 U.S.C. §271(e)(1) when the Court vacated and remanded an earlier Federal Circuit decision that limited the safe harbor. *See Integra LifeSciences I, Ltd. v. Merck KGAA*, 331 F.3d 860 (Fed. Cir. 2003).

The patentee, Integra Lifesciences, alleged that Merck had willfully infringed and induced others to infringe Integra's patents by providing RGD peptides covered by Integra's patents to a research facility. Merck argued that its use of the patented peptides was protected by the common-law research exemption and 35 U.S.C. §271(e)(1). The Federal Circuit agreed with the patentee by ruling that Merck infringed on the patentee's patents on the grounds that 35 U.S.C. §271(e)(1)'s safe harbor does not protect general biomedical research to identify new pharmaceutical compounds. Rather, 35 U.S.C. §271(e)(1) protects only clinical testing undertaken to supply information to the FDA.

On review of the Federal Circuit's ruling, the Supreme Court reversed and held that:

35 U.S.C. §271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drug maker 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."

2005 U.S. LEXIS 4840 (U.S. June 13, 2005). Accordingly, the Supreme Court declined to restrict the applicability of 35 U.S.C. §271(e)(1)'s safe harbor to only uses of patented inventions that are directly related to developing preclinical data of interest to the FDA. Instead, the Court ruled that 35 U.S.C. §271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are "reasonably related" to the development and submission of any information under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).

Although Merck's experimental use of Integra's patented compound did not supply information for submission to the FDA, it did identify the best drug candidate to subject to future clinical testing under the FDA processes. Such activity was found to be "reasonably related" to the process of developing information for submission to the FDA and is now protected under the safe harbor provision of 35 U.S.C §271(e)(1). Future interpretation of "reasonably related" by the Federal Circuit will determine how expansively the experimental use exception will be construed henceforth. For example, courts may expand the ruling of this case to include the use of testing and medical

equipment, including the software thereof, which are “reasonably related” to the process of developing information that is submitted to the FDA during the drug approval process.

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