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Much Anticipated *Merck v. Integra* Decision Provides Broad “Experimental Use” Protection

As many industry observers had predicted, in the closely watched *Merck KGaA v. Integra LifeSciences I, Ltd.* case, the Supreme Court recently interpreted the 35 U.S.C. § 271(e)(1) safe harbor broadly to exempt from infringement the use of patented pharmaceutical compounds and other research tools in testing undertaken for the purpose of obtaining FDA approval for drug products. The Court’s unanimous ruling, issued on June 13, 2005, vacated a Federal Circuit decision that had much more narrowly construed this exemption.

Integra sued Merck for patent infringement in 1996 after Merck entered into an agreement to fund animal trials for a potential cancer therapy utilizing Integra’s patented RGD peptide. Merck argued, among other things, that its activities were protected under the § 271(e)(1) safe harbor provision, which states that

[i]t shall not be an act of infringement to make, use... 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.

A jury found that Merck failed to show that its activities were protected under § 271(e)(1).

On appeal, the Federal Circuit affirmed in a divided opinion, holding that the “experimental use” exemption applies only to clinical testing on human subjects, and not upstream, exploratory research on animals. The court explained that the primary purpose of § 271(e)(1) was to streamline the entry of generic drugs into the market by allowing FDA-required testing on patented drugs before the name-brand patent expired, and that consequently, the exemption does not apply to research not actually submitted to the FDA.

The Supreme Court disagreed with the Federal Circuit’s narrow reading of § 271(e)(1), adopting a more far-reaching interpretation of

the statute. The opinion, authored by Justice Antonin Scalia, states that

[t]he use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis to believe that the compound tested could be the subject of an FDA submission and the experiments will produce the types of information relevant to an IND or NDA.

The Court noted that “[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.” Accordingly, the court held that “preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process” are within the scope of the exemption.

The Court rejected Integra’s argument that the only preclinical data reasonably included in an investigational new drug application (IND) or a new drug application (NDA) is data pertaining to a drug’s safety in humans, and that other preclinical studies relating to a drug’s efficacy, mechanism of action, pharmacokinetics and pharmacology are outside the scope of the safe harbor. The Court explained that while the FDA’s primary objective in reviewing an IND is the safety of the subjects, “it does not follow that the FDA is not interested in reviewing information related to other characteristics of a drug.”

The opinion stressed that “basic scientific research” without the intent or reasonable expectation of developing a particular drug is not “reasonably related” to the development and submission of information to the FDA, and thus is not protected activity. The Court went on to hold that

[i]t does not follow from this, however, that § 271(e)(1)’s exemption from infringement categorically excludes

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either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.

In support of its holding, the Court noted that “Congress did not limit § 271(e)(1)’s safe harbor to the development of information or inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug.” The court observed that “scientific testing is a process of trial and error,” and that “[p]roperly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval.” Further, in instances “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 protected.

Similarly, the Court explained that “it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win the agency’s approval.”

While the Court declined to establish a bright-line rule regarding the scope of the § 271(e)(1) safe harbor, this decision will likely benefit both NDA and ANDA applicants by allowing them access to a wider range of patented research tools and processes without the cost of a license or the threat of infringement litigation. Furthermore, by interpreting the “experimental use” exemption to apply beyond the context of an ANDA, the Supreme Court has given comfort to those engaged in other research and development activities aimed at receiving FDA approval.

ABOUT THE AUTHORS

Keith Parr, Kevin Nelson, David Abramowitz and James Peterka represent pharmaceutical industry companies in litigation, intellectual property and regulatory matters.

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