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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MERCK KGAA *v.* INTEGRA LIFESCIENCES I, LTD., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 03–1237. Argued April 20, 2005—Decided June 13, 2005

It is not "an act of [patent] infringement to . . . 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 . . . use . . . of drugs." 35 U. S. C. §271(e)(1). The Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) is such a law. Under the FDCA, a drug maker must submit research data to the Food and Drug Administration (FDA) in an investigational new drug application (IND) when seeking authorization to conduct human clinical trials, and in a new drug application (NDA) when seeking authorization to market a new drug. Respondents filed a patent-infringement suit, claiming, *inter alia,* that petitioner had willfully infringed their patents by supplying respondents' RGD peptides to other defendants for use in preclinical research. Petitioner answered, among other things, that §271(e)(1) exempted its actions from infringement. The jury found otherwise and awarded damages. In post-trial motions, the District Court affirmed the jury's award and denied petitioner's motion for judgment as a matter of law. The Federal Circuit affirmed that denial, finding that §271(e)(1)'s safe harbor did not apply. It reversed the District Court's refusal to modify the damages award and remanded for further proceedings.

Held: The use of patented compounds in preclinical studies is protected under §271(e)(1) at least 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 statutory text makes clear that §271(e)(1) provides a wide berth for the use of patented drugs in ac-

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tivities related to the federal regulatory process, including uses reasonably related to the development and submission of any information under the FDCA. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 665–669. This necessarily includes preclinical studies, both those pertaining to a drug's safety in humans and those related to, *e.g.,* a drug's efficacy and mechanism of action. Additionally, §271(e)(1) exempts from infringement the use of patented compounds in preclinical research, even when the patented compounds do not themselves become the subject of an FDA submission. The "reasonable relation" requirement cannot be read effectively to limit §271(e)(1)'s stated protection of activities leading to FDA approval for all drugs to those activities leading to FDA approval for generic drugs. Similarly, the use of a patented compound in experiments not themselves included in a "submission of information" to the FDA does not, standing alone, render the use infringing. Because the Federal Circuit applied the wrong standard in rejecting petitioner's challenge to the jury's finding that petitioner failed to show that its activities were covered by §271(e)(1), the trial evidence has yet to be reviewed under the standard set forth in the jury instruction, and developed in more detail here. Pp. 8–15.

331 F. 3d 860, vacated and remanded.

SCALIA, J., delivered the opinion for a unanimous Court.