Column
IP Lawyer

Written by
Charles A Weiss

US Supreme Court decides pharma patent research case

The *Merck v Integra* decision handed down by the Supreme Court in early June is good news for pharmaceutical companies

For more than 20 years the pharmaceutical industry has enjoyed (or been burdened with, depending on one's perspective) a unique provision of the Patent Act – § 271(e)(1) – which provides in part that it is not an act of infringement to make or use 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".

Enacted as part of the Hatch-Waxman Act that established the current regime for the development of generic drugs, the primary use of this provision is by generic manufacturers doing development work on a generic drug before the patent on the branded drug expires. And, of course, the most important federal law that regulates the manufacture and sale of drugs is the Food, Drug and Cosmetic Act administered by the FDA. But the statute as written is not limited to generic drugs and its applicability to certain other situations has been unclear.

One area of dispute was the application of § 271(e)(1) to drug discovery. Stated differently, to what extent is more basic drug research, when any submission to the FDA is years away, subject to the protection of the statute as use of a patented invention "solely for uses reasonably related" to the development and submission of information to the FDA?

In a case that was closely watched by the pharmaceutical industry and academic institutions that conduct drug research, the Supreme Court held that the protection of this section was more generous than some believed.

In *Merck KGaA v Integra Lifesciences*, the Supreme Court addressed the issue of whether the use of a patented invention in pre-clinical research is exempt from infringement under § 271(e)(1) even if the research results are not ultimately submitted to the FDA. The Court of Appeals for the Federal Circuit had held in this case that the research at issue was not exempt from infringement because it was too far removed from an FDA submission, but the Supreme Court read the exemption of § 271(e)(1) more broadly, holding that use of a patented compound is not an act of infringement if there is a reasonable basis for believing the experiments will produce information relevant to FDA submissions.

The case arose from a 1995 agreement between Merck and the Scripps Research Institute under which Scripps would conduct laboratory research on certain compounds with the goal of submitting an Investigational New Drug application, which seeks permission to begin trials in humans, to the FDA within three years. But Integra had several patents on these compounds and sued Merck and Scripps for patent infringement.

The case was tried to a jury, which ruled in favour of Integra and awarded damages of US$15 million. On appeal, the Federal Circuit vacated the damages award as excessive but affirmed the trial court's holding that the research was not protected under § 271(e)(1), explaining that the research was "not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds".

The Federal Circuit's narrow construction of § 271(e)(1) to pre-clinical research generated significant concern and consternation in the pharmaceutical and research communities, and several companies and organisations filed amicus briefs asking the Supreme Court to hear the case, as did the Solicitor General in a brief filed on behalf of the United States and co-signed by the FDA and the Patent and Trademark Office. The Supreme Court accepted the case and in a unanimous decision written by Justice Scalia reversed the decision of the Federal Circuit.

The Supreme Court began with the language of the statute, stating that: "§ 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 [to the FDA]," and therefore, covers preclinical studies. The phase of the research does not determine the applicability of § 271(e)(1).

The Court rejected Integra's argument that the first submission to the FDA (the Investigational New Drug Application) is concerned only with safety and that § 271(e)(1)'s applicability to pre-clinical trials is thus limited to research directed to safety (not research on efficacy, mechanism of action, pharmacokinetics, and pharmacology as conducted by Scripps in conjunction with Merck). Dooming Integra's argument on this point was the government's amicus brief, which represented that such information is submitted to the FDA and is relevant, and often necessary, to its review of an IND.

The Supreme Court further reasoned that the narrow construction of § 271(e)(1) adopted by the Federal Circuit was not correct because it would make the statute's protections illusory by leaving no room for experimentation and failure. Thus, the Court held, if a person conducting research has a reasonable basis for believing that a compound may produce a particular physiological effect, and uses a patented compound in research that, if successful, would be appropriate to include in a submission to the FDA, then the use meets the "reasonable relation" requirement of § 271(e)(1) and does not constitute infringement.

The applicability of § 271(e)(1) to different fact patterns will have to be worked out on a case-by-case basis by the Federal Circuit and the district courts. Indeed, Merck's liability to Integra in this case remains an open question, with the Supreme Court sending the case back to the Federal Circuit for review of the jury's verdict under the Supreme Court's explanation of the correct legal standard. Neither did the Supreme Court's decision address two other controversial issues, one that is specific to pharmaceutical and biotechnology and the other more general.

First, this case did not consider the applicability of § 271(e)(1) to so-called research tool patents when the patented inventions are used in pharmaceutical or biotechnological research. Second, this case did not address the common law research exemption that potentially applies (to the extent it has vitality) to all fields of endeavour.

Thus, while the Supreme Court's decision in this case is of importance in the pharmaceutical and biotechnology fields, the fact that it is limited to the exemption provided by § 271(e)(1) renders it inapplicable to other industries and fields of endeavour.

Charles A Weiss *is a partner in the New York offices of Kenyon & Kenyon.*
cweiss@kenyon.com