Legal Affairs

Is Safe Harbor Closed to Research Tools?
A Receding Scope of Exemption from Patent Infringement

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On August 5, in Proveris Scientific Corp. v. Innovasystems, Inc., the Federal Circuit affirmed a judgment of infringement liability that has broad implications in the pharmaceutical and medical device fields. As a result of the Federal Circuit’s holding, the safe-harbor provisions of 35 U.S.C. § 271(e)(1) are not available for patent infringement protection against the use of patented tools that do not require FDA premarket approval. Therefore, the ruling can be seen as favorable to entities seeking to sell or license patented tools useful for conducting regulatory-associated research.

The device at issue in the Proveris case involved a system and apparatus for measuring aerosol spray characteristics such as those commonly used in various nasal spray and inhaler drug-delivery devices. While the measurement device itself is not subject to FDA approval, it is used for generating the data necessary for FDA approval of the inhaler-based drug delivery devices.

Proveris holds a patent on such an aerosol-testing apparatus and system (U.S. patent 6,785,400). Innovasystems sold a device alleged to infringe the Proveris patent.

When Proveris sued Innovasystems for patent infringement, Innovasystems argued that since the equipment was only used in connection with the development and submission of information to the FDA, the equipment was covered under the safe-harbor provisions of § 271(e)(1). The Federal Circuit, however, determined that a patent infringement defendant has no immunity for liability under the safe-harbor provisions if its testing device is not subject to an FDA premarket approval process.

Safe Harbor

Legislators in the mid 1980s recognized that the rigors of the FDA premarketing approval process were preventing generic pharmaceutical products from efficiently entering the market despite expiration of the underlying patents.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, also referred to as the Hatch-Waxman Act, primarily to balance incentives for pharmaceutical firms to make the investment to develop new drug applications through limited patent term extension provisions based on regulatory market delays, with additional provisions for generic drug companies to file abbreviated new drug applications to bring cheaper versions of drugs to market after patent expiration.

Section 271(e)(1) provides protection for generic drug competitors from precommercial sales infringement as long as their activities are “reasonably related to the development and submission of data under a Federal Law.”

By its language, however, § 271(e)(1) is not limited to entities seeking to produce generic drugs and has been invoked by innovator and generic drug and medical device entities seeking to use any third-party patented invention so long as the use is “reasonably related” to the development and submission of information for FDA approval.

Determining the extent of the safe harbor protection from patent infringement has been the source of much legal debate. It was initially understood that §
Extensions of patent term can be obtained for new drugs for human or animal use, new Class III medical devices, and new food or color additives. The Federal Circuit extended the safe-harbor protections of § 271(e)(1) to Class I and/or Class II medical devices, stating that the language of § 271(e)(1) makes no distinction among the different FDA classes of medical devices or drugs (AbTox v. Exitron).

The courts have also broadly interpreted which product development activities are reasonably related to FDA approval for the purposes of § 271(e)(1) protection. For example, the Federal Circuit held that merely demonstrating an implantable defibrillator at medical conferences was reasonably related to FDA approval, because it facilitated the selection of clinical trial investigators.

In 2005, the U.S. Supreme Court held that a reasonably related activity does not require the eventual submission of the information to FDA. Rather, it also includes preclinical activities to determine a composition's mechanisms of action, pharmacokinetics and pharmacology, and findings of possible unfavorable and unintended side effects—all of which would be appropriate to include in a submission to the FDA.

The Federal Circuit stated in Proveris that Congress enacted the safe-harbor provision of the Hatch-Waxman Act to eliminate “two unintended distortions” of the effective patent term resulting from the regulatory approval process of the FDA under the Federal Food, Drug, and Cosmetic Act. The first was to extend the patent term of patents covering products subject to regulatory delays caused by the FDA approval process. The second was to insulate from infringement liability actions for purposes that are reasonably related to an FDA submission.

The court reasoned that equipment ancillary to the FDA’s approval process is not subject to the “two unintended distortions” contemplated by § 271(e)(1). Because the patent holder did not need FDA approval for its testing device, the patent holder faced no limitations to use its product at the start of the patent term. Likewise, the defendant’s accused device is also not subject to FDA approval, so any infringement by that device cannot be sheltered by § 271(e)(1).

Hence, the infringing device was not itself subject to FDA approval, but was used to perform tests during drug research and development for FDA approval. The Federal Circuit held that the safe-harbor provision applied only to products that themselves are subject to FDA premarket approval, which face the unintended distortions to an effective patent term.

**Future Implications for Research Tools**

The Proveris decision would appear to conflict with at least some of the dicta statements made by the Supreme Court in Merck v. Integra, which broadly interpreted the scope of the safe harbor, and further judicial clarification may be necessary with respect to infringement liability for any particular research tool on a case-by-case basis.

The Supreme Court previously stated that the safe harbor would not protect “basic scientific research performed without an intent to develop a particular drug or a reasonable belief that the composition will cause the sort of physiological effect the researcher intends to induce” as not reasonably related to the development and submission of information to the FDA. Nonetheless, the Supreme Court paradoxically indicated that the use of the patented molecule in Merck as a positive control for screening other molecules as drug candidates was not such a research tool, and therefore, would be entitled to safe-harbor protection. Apparently, earlier-stage drug discovery research tools may qualify for the safe harbor infringement exemption more readily than later-stage premarketing compliance tools.

Research tools were defined by the 1998 NIH Working Group on Research Tools as “embracing the full range of resources that scientists use in the laboratory.”

The implications in Proveris for the use of research tools to develop and test products for purposes of obtaining data for FDA approval could be far-reaching. If a company is using a patented device as a research tool for the purposes of obtaining data in conjunction with regulatory approval, that use may not be immunized under the safe-harbor provisions of § 271(e)(1).

As such, drug manufacturers and medical device developers who relied on the safe harbor provisions as a defense to infringement claims since the Merck decision should now reevaluate their use of others’ patented research tools, especially if the research tool itself is not subject to regulatory review. This ruling will likely increase implementation costs for drug and medical device manufacturers.

On the other hand, patent holders for research tools are likely to welcome the Proveris decision as limiting the scope of the noninfringement safe-harbor provisions. While the Federal Circuit did not squarely address the “research tool patent” question for all situations, research tool patent owners may be able to rely on this decision to increase enforcement of their patents.