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Reining In The Scope Of Safe Harbor

Law360, New York (August 08, 2008) -- In a decision sure to be welcomed by many research tool patent holders, the Federal Circuit, in Proveris Scientific Corp. v. Innovasystems Inc. (Aug. 5, 2008), departs from a line of cases that have expansively interpreted the "safe harbor" provisions of the Hatch-Waxman Act.

The decision reins in the scope of the safe harbor, finding that it does not reach devices that are not themselves subject to an FDA pre-market approval process, even if they are used to obtain data for FDA submissions.

While not directly addressing the "research tool patent" question, the decision will be welcomed by research tool patent owners, who may be able to rely on the decision to enforce patented technology that is primarily used in drug development.

Indeed, this case seems to strike more of a balance between the rights of patent holders and the needs of those seeking FDA approval for drugs or medical devices.

The Proveris patent relates to analytical devices useful for characterizing aerosol sprays used in drug delivery devices, such as nasal sprays and inhalers.

The devices can be used to obtain data on such drug products that are submitted to the FDA during the premarket approval process.

The devices themselves are not subject to FDA approval, and so the Proveris patent was not eligible for a patent term extension under the Hatch-Waxman Act. Innovasystems sold a device alleged to infringe the Proveris patent.

In defense of those charges, Innovasystems asserted that the safe harbor shielded it from infringement liability because its devices are used "solely for the development and submission of information to the FDA." The Federal Circuit held otherwise.

The statute at issue provides that "[i]t shall not be an act of infringement to make, use, offer to sell or sell ... 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."

While recent decisions have wrestled with the "solely for uses reasonably related to" language, the Proveris decision focuses on the "patented invention" language, and interprets that language in light of the legislative history of the Hatch-Waxman Act.

As summarized by the Federal Circuit (discussing the Supreme Court's decision in Eli Lilly & Co. v. Medtronic, Inc.), the patent term extension (35 U.S.C. §156) and safe harbor (35 U.S.C. §271(e)(1)) provisions of the Hatch-Waxman Act "were enacted in order to eliminate two unintended distortions of the effective patent term resulting from premarket approval required of certain products."

The first distortion occurs at the front end of a patent's term, when the lengthy FDA approval process can delay market entry until well after the patent has issued.

Section 156 addresses this distortion by providing for patent term extension when FDA approval is not obtained until after the patent issues.

The second distortion occurs at the end of a patent's term, when the patent holder might continue to enjoy market exclusivity after the patent expires because would-be competitors could not complete the FDA approval process without risking liability for patent infringement.

Such liability could arise, for example, from using the patented drug in comparative testing.

The safe harbor addresses this distortion by excluding from infringement activities related to obtaining information for the FDA approval process.

With this legislative history in mind, the Federal Circuit determined that Congress did not intend the safe harbor to apply to parties like Innovasystems, who were "not seeking FDA approval for a product in order to enter the market to compete with patentee," whose product was "not subject to FDA premarket approval," and who, even without the Hatch-Waxman Act, would not "have been adversely affected by the second distortion."

The court also noted that Proveris is not an entity who, without the Hatch-Waxman Act, would "have been adversely affected by the first distortion," and that Proveris' patent is not subject to extension under §156.

The court thus concluded that the Innovasystems device is not a "patented invention" as used in the statute, and so is not sheltered by the safe harbor.

Patent holders, particularly research tool patent holders, are likely to welcome the Proveris decision as limiting the reach of the safe harbor.

Indeed, with no correlation required between patented inventions subject to the safe harbor and products subject to premarket approval or patent term extension, the safe harbor theoretically could reach laboratory equipment such as “microscopes, analytical balances [and] computers,” as Proveris argued.

Such an application of the safe harbor could severely impact the value of research tool patents whose primary use is in the context of drug development, and could stifle the development of research-related technology.

The Proveris decision provides some assurance that the Federal Circuit will not let the safe harbor vitiate the value of all research tool patents.

The decision also may encourage innovators to seek patents on their research-related inventions, instead of maintaining them as trade secrets out of concern that patents would not be enforceable.

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