PUBLICATION

Federal Circuit: No § 271(e)(1) Safe Harbor for Patented Inventions not Regulated by FDA

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The United States Court of Appeals for the Federal Circuit ruled August 5, 2008 that the 35 U.S.C. § 271(e)(1) "safe harbor" does not immunize accused activity from infringement of patented inventions that are not subject to FDA regulation. *Proveris Scientific Corp. v. Innovasystems, Inc,* No. 2007-1428, 2008 WL 2967100 (Fed. Cir. Aug. 5, 2008).

In the *Proveris* case, Proveris Scientific Corporation (Proveris) is the owner of a patent "directed to a system and apparatus for characterizing aerosol sprays commonly used in various drug delivery devices …." Characterization of such sprays is an important component of the Food and Drug Administration (FDA) regulatory approval process for various aerosol delivery devices under the Federal Food, Drug, and Cosmetic Act (FDCA). Innovasystems, Inc. (Innova) makes and sells the Optical Spray Analyzer (OSA), which measures certain parameters of aerosol sprays. Although the OSA device is not subject to FDA approval, it is used in the development of data submitted to FDA.

Proveris filed suit against Innova, alleging infringement of its patent. Innova countered that its activities fell within the safe harbor provisions of 35 U.S.C. § 271(e)(1), which states, in relevant part:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States 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 or veterinary biological products.

35 U.S.C. § 271(e)(1) (West 2008). Innova asserted that its allegedly infringing activities fell within the safe harbor because its OSA devices are used by third parties solely for the development and submission of information to FDA. The District Court disagreed, ruling as a matter of law that § 271(e)(1) does not immunize the OSA device from infringement of the Proveris patent.

On appeal, the Federal Circuit affirmed. The court explained that 35 U.S.C. §§ 156 and 271(e)(1), two key provisions of the Hatch-Waxman Act, counterbalance one another by eliminating "two unintended distortions of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA." The first distortion was the reduction of effective patent life at the beginning of patent term due to the FDA premarket approval process, and is addressed by § 156, which states, in relevant part:

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent … if – ….

(4) the product has been subject to a regulatory review period before its commercial marketing or use ….

35 U.S.C. § 156 (West 2008). The second distortion was the de facto extension of effective patent life at the end of patent term, also due to the FDA premarket approval process, which delayed competitors' entry to the market. This distortion is addressed by the safe harbor of § 271(e)(1). The Federal Circuit noted, though, that

"Innova's infringement is not for purposes of its own FDA-related research, but rather for commercial sale to third parties engaged in such research." The court then defined the limits of the § 271(e)(1) safe harbor when it observed that drug delivery devices tested by the OSA device are subject to FDA premarket approval, but the OSA device itself is not:

"Because [Innova's] OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion …. [S]o too Proveris is not a party who, prior to enactment of the Act, could be said to have been adversely affected by the first distortion ... because [it] is not a patentee who would have been faced with a reduction of effective patent life caused by the FDA approval process."

Thus, "Proveris's patented product … is not eligible for the benefit of the patent term extension" of § 156, and Innova's OSA device "does not need the safe harbor protection" of § 271(e)(1).

Observations

After the *Proveris* decision, medical device and pharmaceutical manufacturers must be alert to the possibility that devices or products — which they believed were immunized from infringement by the safe harbor afforded by § 271(e)(1) — may only be immune if the devices or products are themselves subject to regulation under the FDCA.

The Federal Circuit's opinion also leaves open the question of whether a third party that makes an allegedly infringing device, but uses that device entirely in-house and "solely for uses reasonably related to the development and submission of information" to FDA, can claim immunity under § 271(e)(1). Could Innova have received funding from a third party to make and use an OSA device entirely in-house and solely for activities related to FDA submissions? This scenario is similar to the facts of *Merck KGaA v. Integra Lifesciences I, Ltd.*, in which the Supreme Court found that peptides manufactured by a university professor (under a grant from Merck KGaA) and used in his preclinical studies were immunized under § 271 (e)(1) from infringement of Integra's patents so long as there was a reasonable basis for believing that the studies could be the subject of an FDA submission. 545 U.S. 193 (2005). Unlike the OSA device in *Proveris*, though, the peptides in the *Merck* case could have been "eligible for the benefit of the patent term extension" of § 156.

In sum, the Federal Circuit's decision in *Proveris*, together with the Supreme Court's decision in *Merck*, suggests that the § 271(e)(1) safe harbor is available so long as: (1) the alleged infringer has a reasonable basis for believing that its allegedly infringing activities could provide information that would be appropriate to include in a submission to FDA; and (2) either the patented invention or the allegedly infringing product could themselves be subject to a required FDCA approval process.