

## Patents/Infringement

### § 271(e)(1) Safe Harbor Applies Only If Device Is Subject to FDA Approval

A patent infringement defendant has no immunity from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1) if its accused device is not subject to premarket approval by the Food and Drug Administration, the U.S. Court of Appeals for the Federal Circuit ruled Aug. 5 (*Proveris Scientific Corp. v. Innova-systems Inc.*, Fed. Cir., No. 2007-1428, 8/5/08).

Affirming a judgment of infringement liability, the court relied on the Supreme Court's 1990 ruling in *Eli Lilly & Co. v. Medtronic Inc.* to explain the interplay between the Patent Act's Sections 156 and 271(e)(1). While Section 156 provides a patent term extension to adversely affected patentees who received a shorter term length while seeking FDA approval, Section 271(e)(1) was enacted to shelter those seeking FDA approval in order to enter the market to compete with patentees, the court noted.

Observing the symmetry between these statutes, the court said that the patentee in this case is not eligible for the benefit of a longer patent term because its patented aerosol analyzer is not subject to FDA approval. Likewise, the defendant's accused device is also not subject to FDA approval, and any infringement by that device cannot be sheltered by Section 271(e)(1), the appellate court reasoned.

The *Proveris* decision reverses the trend in the courts toward broadening the protection from liability under the safe harbor for infringing acts in drug and medical device development, an expert told BNA.

**Aerosol Spray Analyzer.** Proveris Scientific Corp. has a patent (6,785,400) on an apparatus and system for analyzing aerosol sprays commonly used in various drug delivery devices, such as nasal spray pumps and inhalers.

Innovasystems Inc. sells a device known as the Optical Spray Analyzer, which measures the physical parameters of aerosol sprays used in the delivery of nasal sprayers.

Proveris sued Innova for patent infringement. Innova invoked the safe harbor provision of the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act, codified at 35 U.S.C. § 271(e)(1), and asserted patent invalidity for anticipation under Section 102 of the Patent Act and for obviousness under Section 103.

Judge William G. Young of the U.S. District Court for the District of Massachusetts ruled as a matter of law that Section 271(e)(1) does not immunize Innova's OSA devices from infringement of the '400 patent. Further, the court granted Proveris a judgment as a matter of law as to infringement of Claims 3-10 and 13 of the '400

patent, and granted Proveris a JMOL on Innova's invalidity defenses.

Although the jury awarded no damages for infringement of Claims 3-10 and 13, the district court entered final judgment of infringement and issued a permanent injunction against Innova.

Innova appealed.

**Two 'Distortions' Solved by § 156 and § 271(e)(1).** Section 271(e)(1) of the Patent Act provides that:

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.

Innova's OSA device is not subject to approval by the Food and Drug Administration. Still, Innova insisted that its alleged infringement is immune under this provision because its OSA device is used by third parties solely for the development and submission of information to the FDA.

In addressing this question, the Federal Circuit found "instructive" the Supreme Court's ruling in *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 15 USPQ2d 1121 (1990) (40 PTCJ 173, 185, 6/21/90). From that case, the appellate court observed that Sections 156 and 271(e)(1) of the Patent Act were enacted to eliminate "two unintended distortions" of the effective patent term resulting from premarket approval required of certain products pursuant to the FDCA.

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**"Because the 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," Judge Alvin A. Schall wrote.**

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Judge Alvin A. Schall noted as follows:

- Section 156 was enacted to cure the first distortion—the reduction of effective patent life caused by the FDA premarket approval process. "The first distortion adversely affected patentees," he said.

- Section 271(e)(1) was enacted to cure the second distortion—the de facto extension of effective patent life at the end of the patent term also caused by the FDA premarket approval process. This "second distortion adversely affected those seeking FDA approval in order to enter the market to compete with patentees," he continued.

**Device Not Subject to FDA Approval Has No Shelter.** Noting that the second distortion is relevant to this case, the court went on to hold that Innova was not entitled to the safe harbor of Section 271(e)(1) because its de-

vice is not subject to FDA premarket approval. Schall explained:

As far as the second distortion is concerned, Innova's OSA device is not subject to FDA premarket approval. Rather, FDA premarket approval is required only in the case of the aerosol drug delivery product whose spray plume characteristics the OSA measures. In short, Innova is not a party seeking FDA approval for a product in order to enter the market to compete with patentees. Because the 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. For this reason, we do not think Congress could have intended that the safe harbor of section 271(e)(1) apply to it. Put another way, insofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief. We thus agree with the district court that Innova is not entitled to the benefit of the section 271(e)(1) safe harbor.

**Proveris Not Affected by Term Reduction.** Just as 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, Proveris is not a party who, prior to enactment, could have been adversely affected by the first distortion, Schall continued.

"That is because Proveris is not a patentee who would have been faced with a reduction of effective patent life caused by the FDA approval process, the reason being that the invention claimed in the '400 patent is not subject to the premarket approval required by the FDCA," he explained, adding:

We think this is significant because, as noted above, in *Eli Lilly* the Court spoke of its interpreting the phrase "patented invention" in section 271(e)(1) to include all products listed in section 156(f) as producing a "perfect 'product' fit" between the two provisions. . . . The result we reach today achieves the same kind of fit, or symmetry. Because Proveris's patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).

Given this reasoning, Innova's argument that it is entitled to the safe harbor because it is offering for sale and selling a "patented invention" must be rejected, the court said. Since Proveris's patented product is not subject to FDCA approval, it is not a "patented invention" for purposes of Section 271(e)(1), and thus the accused OSA is not being used in a way "reasonably related" to the "development and submission of information" under the language of the statute, the court concluded.

Having agreed with the district court's conclusion that Innova had no shelter under Section 271(e)(1), the appellate court went on to uphold the grant of the JMOL in favor of Proveris on infringement and the invalidity defenses.

The district court's ruling was affirmed.

The opinion was joined by Judges William C. Bryson and Arthur J. Gajarsa.

**Proveris, Practitioner React.** Dino J. Farina, president of Marlborough, Mass.-based Proveris, welcomed the Federal Circuit's ruling, saying in a statement, "We are gratified that the appeals court has also recognized the validity of our intellectual property and affirmed the permanent injunction to prevent InnovaSystems' further infringement."

The impact of the *Proveris* decision is likely to reverberate beyond just Proveris and Innova, according to Kathleen Petrillo, a partner at Senniger Powers in St. Louis. As a result of the *Proveris* decision, Petrillo said, "Research tool companies may be able to attract more venture and seed capital now that investors are assured that the [safe harbor] exemption will not apply to patented inventions that don't require FDA approval."

"Many early stage investors have steered away from research tools due to the uncertainty created by the Supreme Court's *Merck* decision [*Merck KGaA v. Integra Lifesciences I Ltd.*, 545 U.S. 193, 74 USPQ2d 1801 (2005) (70 PTCJ 198, 6/17/05)]," Petrillo told BNA Aug. 8, "but, now, it may be an area where 'angels' no longer fear to tread."


However, Petrillo observed, even if *Proveris* is welcome news to research tool companies, it could increase the drug development costs for drug and medical device manufacturers.

"Drug manufacturers who relied on the safe harbor provision to immunize their drug development process from infringement now have to reconsider their use of research tools and assess their freedom to operate in view of relevant research tool patents," Petrillo said. "Some drug manufacturers may decide that their limited use of a research tool on the road to drug discovery could not result in significant damages for infringement, and may continue their activity despite the *Proveris* decision."

But, Petrillo said, the question of damages could change considerably if the research tool at issue is the only means available for discovering the drug. Under this scenario, in which a research tool company could argue that it is entitled to significant damages since the drug manufacturer may have never discovered the drug without the patented research tool, a drug manufacturer might decide to take a license under the patent. In turn, the licensing costs would increase the drug manufacturer's drug development costs, she said.

Proveris Scientific was represented by its general counsel, Susan H. Farina of Marlborough, Mass. InnovaSystems was represented by Stephen P. Pazan of Spector Gadon & Rosen, Moorestown, N.J.

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