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On August 5, 2008, the Federal Circuit issued an opinion attempting to create statutory symmetry between two Hatch-Waxman Act provisions that sought to eliminate two distortions caused by the Food Drug and Cosmetic Act ("FDCA"). In so doing, the decision deviates from earlier cases that expressed an expansive interpretation of Hatch-Waxman.

The court’s decision clarifies the Hatch-Waxman’s safe harbor provision, 35 U.S.C. §271(e)(1), by looking at the patent term extension section, 35 U.S.C. §156. Both provisions were intended to eliminate distortions in the patent system.

The first distortion occurred because patent applications are filed early in the regulatory process, but market entry is delayed until regulatory review is completed. As a result, the early years of the patent term are sometimes consumed obtaining premarket approval for the patented invention, rather than generating profits. The patent term extension provision eliminated this loss of part of the patent term for those patents claiming a product subject to U.S. Food and Drug Administration ("FDA") premarket approval.

The safe harbor provision sought to eliminate a second distortion, due to the de facto extension of the patent term caused by the fact that competitors could not begin the process for obtaining FDA approval until after the patent expired. The safe harbor provision, codified at 35 U.S.C. § 271(e)(1), 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.

The Court’s decision: Patented inventions not subject to FDCA approval do not qualify for safe harbor protection nor are such patented inventions eligible for patent term extension under Hatch-Waxman.
Background Facts
Proveris Scientific Corporation (“Proveris”) owns U.S. Patent No. 6,785,400 for a system and apparatus used to characterize aerosol sprays used in drug delivery devices. Although the FDA requires approval for inhaler-based drug delivery devices, the system and apparatus claimed in Proveris’ patent are not themselves subject to FDA approval.

Proveris sued Innovasystems, Inc. (“Innova”) over Innova’s sales of a “spray data acquisition system” for measuring the physical parameters of aerosol sprays used in nasal spray drug delivery devices. The Innova device, an Optical Spray Analyzer (“OSA”), was only used for basic research and for generating data for FDA submissions. The OSA was not itself subject to FDA approval.

Lower Court Ruling
Innova pointed out that the device was intended to generate data required by the FDA and was only sold to pharmaceutical companies. Thus, Innova argued, the device fell squarely within the plain meaning of §271(e)(1).

Proveris asserted that §271(e)(1) does not cover laboratory equipment, but is limited to what it refers to as “products”—drugs, medical devices, food additives and color additives regulated by the FDA. In the alternative, Proveris argued that Innova did not fall within the exemption because it was not generating data for submission to the FDA, but rather, selling equipment used by others to generate such data.

The district court sided with Proveris, and ruled that the OSA is not a “patented invention” within the meaning of the statute. The court therefore held that Innova was not entitled to the §271(e)(1) exemption as a matter of law. Consequently, the court found infringement and issued a permanent injunction, but declined to award damages.

The Federal Circuit Affirms Lower Court Ruling.
On appeal, the Federal Circuit affirmed the district court’s ruling interpreting the safe harbor provision as excluding Innova from its protection.

The Federal Circuit determined that “patented invention” and “reasonably related” were the critical terms in 35 U.S.C. §271(e)(1). The Supreme Court, in *Eli Lilly & Co. v. Medtronic, Inc.*,¹ had stated that the phrase “patented invention” included all products listed in §156(f). The Supreme Court also noted that all the products eligible for patent term extension under §156 were subject to FDA approval, including drugs, medical devices, food additives, and color additives. In *Merck KGaA v. Integra Lifesciences I, Ltd.*,² the Supreme Court opined that the “reasonably related” activity does not require actual submission of information to the FDA, but included situations in which a party has “a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular effect, and uses that compound in research that, if successful, would be appropriate to include in a submission to the FDA....”

Innova argued that it was entitled to protection under §271(e)(1) because its offering for sale and sale of a “patented invention” (“the OSA device”) was “reasonably related” to the “development and submission

of information" pertinent to the FDA premarket approval required for inhaler-based drug delivery devices. The Federal Circuit found Innova’s argument was flawed because the device claimed in Proveris’ patent was not a “patented invention” for purposes of §271(e)(1) and therefore Innova’s sale of the OSA device was not exempt from infringement.

The Federal Circuit explained:

Innova’s OSA device was 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, [the Court did 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.

Hence, the court affirmed that Innova was not entitled to the shelter of the safe harbor provision.

How Has the Interpretation of the Safe Harbor Provision Changed?

Congress enacted 271(e)(1) primarily for the purpose of exempting generic drug companies from infringement liability for testing a patented drug prior to patent expiration for the purpose of generating the data necessary for FDA approval. However, because the language of the statute is much broader, the courts have interpreted the statute as covering more than just patented drug candidates.

For example, in Eli Lilly, the Supreme Court held that the term “patented invention” under §271(e)(1) exemption meant all inventions within section 156 §271(e)(1), which included medical devices. In Abtox, Inc. v. Exitron Corp., the Federal Circuit adopted a broader interpretation than the Supreme Court had in Eli Lilly, concluding that the phrase “patented invention” under §271(e)(1) covers any medical device, regardless of its eligibility for patent term extension under §156.

In Merck, the Supreme Court indicated that §271(e)(1) potentially reached any invention used in the generation of data that might reasonably be appropriate for FDA submission. In that case, the Court held that Merck’s use of Integra’s RGD peptide as a “positive control” against which to measure the efficacy of experimental drug candidates was exempt from infringement under §271(e)(1).

Proveris is arguably a narrower decision than Abtox. In Proveris, the Federal Circuit reasoned that the term “patented invention” for purposes of §271(e)(1) does not include devices that are not subject to a required FDCA approval process. Further, the Proveris decision reads §156 and §271(e)(1) symmetrically. Proveris’s patented product is not subject to FDCA approval and, thus, is not eligible for patent term extension under §156. Consequently, because Innova’s OSA device is not subject to FDCA approval, it is not eligible for safe harbor protection under §271(e)(1).

122 F.3d 1019 (Fed. Cir. 1997).
Below is a pictorial representation of the scope of inventions qualifying for patent term extension under §156 and safe harbor under §271(e)(1). Innova’s product falls outside of both of these Hatch-Waxman provisions.

What Impact Will the Proveris Decision Have on Research and Development?

Under the Federal Circuit’s ruling, companies selling an apparatus not subject to FDA approval that is covered by a third-party patent should tread lightly. It appears that those sales will not be exempt from infringement under §271(e)(1).

Conceivably, the result in Proveris may not open the floodgates for future litigation over non-FDA approvable products. In deciding whether to litigate or license, the patentee of an apparatus not subject to FDA submission should take note that Proveris was only awarded a permanent injunction, and not monetary damages. Yet, to achieve this result, Proveris most likely spent large sums of money on the litigation. Consequently, in view of the cost and benefits of this type of litigation, it may be appropriate to opt for licensing rather than litigation.

It still remains unclear whether the use of research tools, such as diagnostic assays used to screen drug candidates, would be exempt from infringement under §271(e)(1). Research tool patentees should stay tuned for further developments.

In any event, the decision may encourage inventors of research-related inventions to seek patent protection rather than rely on other forms of protection, such as trade secrets.

Conclusions

The Federal Circuit clarified the §271(e)(1) safe harbor exemption where a patented device can be used for both basic research and for generating data for FDA submission. An infringing seller of such a device is not protected by the §271(e)(1) safe harbor exemption even if its customers are notified that they are only authorized to use the device for activities reasonably related to generating data for FDA unless the device itself is subject to FDA approval.