The Applicability of the Hatch-Waxman Safe Harbor to Research Tool Patents

Pharmaceutical Intellectual Property Summit

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Safe Harbor Provision

“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).

Purpose of § 271(e)(1) was to overrule Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), which precluded experimentation necessary to obtain FDA approval before all relevant patents expired even if the drug product were commercialized after such patents expired.

The legislative history of the Hatch-Waxman Act states that § 271(e)(1) authorizes a “limited amount of testing” such that “the nature of the interference” with the rights of a patentee would not be “substantial,” but only “de minimis.” Thus, “[t]he patent holder [would] retain the right to exclude others from the major commercial market place during the life of the patent.”
Patent Term Extension

Section 156(a), part of the Hatch-Waxman Act, allows an extension of the term of a patent to compensate the patentee for the time (or at least a portion of it) that the patented product (or its use) was subject to regulatory review before commercial marketing or use was permitted.

Purpose of §156(a) was to allow a patentee to recoup patent term that was lost awaiting FDA approval to commercialize the patented product.

Unlike § 271(e)(1), which covers “patented inventions,” § 156(a) only includes product patents (which include medical devices and biologics), patents covering the use of an approved product, or methods for manufacturing an approved product.

Research tool patents are not covered.
Research Tools

NIH defines research tools as items that “scientists use in the laboratory... [including] cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry and DNA libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases and computer software.” Report of the NIH Working Group on Research Tools (1998).

In the original Federal Circuit decision in Merck v. Integra and in his dissenting opinion on remand, Judge Rader focused on the particular use of a patented invention – not its inherent characteristics – as determining whether it should be characterized as a “research tool.”

On remand, Judge Rader states that research tools have “one and only use” – “to test and ascertain information about candidate compounds.”
Integra Lifesciences, Ltd. v. Merck Kgaa

MERCK I (331 F.3d 860 (Fed. Cir. 2003))
- Allowing safe harbor to “swallow” the use of research tool patents would “deprive entire categories of inventions of patent protection.”
- “Certain uses” of a patented compositions, e.g., peptides, can render the composition a “laboratory [i.e., research] tool.” Particular type of use of the invention is key.

MERCK II (545 U.S. 193 (2006))
- Safe harbor provides “wide berth” of protection for the use of patented drugs in FDA-related activities.
- Safe harbor extends to “all uses of patented inventions” in FDA-related activities.

MERCK III (496 F.3d 1334 (Fed. Cir. 2008))
- Stresses that scientist must have reasonable basis for believing that compound may work for its intended purpose to satisfy the statutory test.
- Type of particular test will not be determinative.
- Cell receptors do not operate as compounds for FDA approval, but rather as experimental targets to test for attachment characteristics (Rader dissent). Again, it is the type of use of a patented invention – even if it is a compound – that determines whether it is a “research tool.”
Proveris Scientific Corp. v. Innovasystems, Inc.,
536 F.3d 1256 (Fed. Cir. 2008)

Patent-in-suit covered system and apparatus for characterizing aerosol sprays used in drug delivery systems. The patented device was not subject to FDA approval. Innovasystems sold patented devices to other companies who used them to gather information for FDA submission. District Court found safe harbor did not apply.

On appeal, Proveris argued that the safe harbor did not apply to research tool patents because such patents cannot be extended under § 156(a). In addition, since Innovasystems did not itself gather the data for FDA submission, safe harbor did not apply.

Innovasystems argued that the safe harbor applies to all “patented inventions.” Moreover, “sales” to third parties are contemplated because “sales” are specifically exempted by the statute. Thus, safe harbor exemption is not limited to the organizations that themselves gather data for FDA submission.

The second argument was never addressed.
Proveris v. Innovasystems

The Federal Circuit stated that interpreting the phase “patented invention” in § 271(e)(1) to include all products in § 156(a) produced a “perfect product fit” between the two sections.

But in Abtox v. Exitron, 122 F.3d 1019 (Fed. Cir. 1997), the Federal Circuit held Class II medical devices – not subject to patent term extension – were still “patented inventions” within the § 271(e)(1). See also Chartex v. MD Personal Prod. Corp., 5 F.3d 1505 (Fed. Cir. 1993) (court will not read limitations from § 156(a) into § 271(e)(1)).

Q: “[W]hether § 271(e)(1) immunizes the manufacture, marketing or sale of Innova’s OSA, which is used in the development of FDA regulatory submissions, but is not itself subject to the FDA premarket approval process.”
Proveris v. Innovasystems

Two so-called “distortions” addressed by the Hatch-Waxman Act:

(i) De facto extension of the patent term caused by FDA approval of competing products (the Roche v. Bolar situation); and

(ii) Loss of patent term due to FDA approval of patented product.

* * *

“Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry before patent expiration, Innova is not a party who, prior to the enactment of the Hatch-Waxman Act, could be said to have been adversely affected by [distortion rectified by § 271(e)(1)] ... 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.”
Proveris v. Innovasystems

“Proveris is not a patentee who would have loss patent life due to FDA approval because its patented product was not subject to FDA premarket approval process. Thus, Proveris is not a party who, prior to Hatch-Waxman would have been adversely affected by this distortion.” Accordingly, the Federal Circuit held that the Proveris patent was not subject to an extension under § 156(a), therefore, it was not a “patented invention” under § 271(e)(1).

Is reading the limitations of § 156(a) into § 271(e)(1) correct as a matter of statutory interpretation?

Do you need to meet both tests (fail both tests) before Hatch-Waxman does not apply?

What if there is no “substantial interference” with the rights of the patentee?
Hypothetical: Proteins

Proteins are subject to pre-marketing approval if used as a therapeutic.

Would the use of a protein in a pre-clinical test to acquire data to obtain FDA approval for a different drug be within the safe harbor? *E.g.*, as a reference standard?

Arguments both ways:

First, because FDA approval is *not* needed to use the protein as a “tool,” the safe harbor does not apply. According to *Proveris*, first distortion is not present.

Second, since FDA approval is needed to market a protein as a therapeutic, a patent covering that protein is theoretically subject to a § 156(a) extension. Thus, it may be a “patented invention” within § 271(e)(1), even under *Proveris*. 

Thank You