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Research Tool Patents: A Light At The End Of The Tunnel?

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In *Merck KgA v. Integra Life Sciences I, Ltd.*, the Supreme Court held that the safe harbor under 35 U.S.C. § 271(e)(1) extended to the use of patented compounds in pre-clinical studies, provided there is a reasonable belief that the experiments would provide information relevant for submission to the F.D.A.[1] However, the Court declined to reach the question of whether infringement of so-called "research tool" patents would also fall within this safe harbor. The Federal Circuit's recent decision in *Proveris Scientific Corp. v. InnovaSystems, Inc*. suggests that life sciences companies holding research tool patents need not fear that competitors may infringe them with impunity.[2]

Research tools are reagents or methods that are useful in conducting experiments but are not diagnostic or therapeutic products or commercial scale production processes themselves. Common research tools may include cell lines, transgenic animals, particular DNA or protein sequences, libraries of chemicals, DNAs, or proteins, or even databases and software.

In *Proveris*, the Federal Circuit was faced with the question of whether an accused infringer's activity fell within the 271(e)(1) safe harbor where the patent at issue concerned a device to test drugs for FDA regulatory submissions. Thus, unlike in *Merck*, where the patented item was used as a control in experiments submitted to the FDA, Innova manufactured the patented item for others to use to obtain data for FDA submissions. Innova's product is a research tool as it was designed to help analyze other therapeutics.

In deciding *Proveris*, the Federal Circuit articulated a new, more stringent standard for determining when the safe harbor applies. The court anchored this standard in the relationship between the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Hatch-Waxman Act in which the safe harbor is found. According to the Federal Circuit, the Hatch-Waxman Act aimed to correct two distortions in the FDCA: First, FDA review of drugs precluded patentees from generating profits early in the patent term. Second, because of FDA pre-market approval, the effective patent term was lengthened because competitors could only start obtaining FDA approval once the patent term was over. Section 156 of Hatch-Waxman provides for patent term extensions due regulatory delays, addressing the first distortion. Section 271(e)(1) sought to eliminate "de facto" patent term extension by immunizing competitors' activities "reasonably related" to FDA submissions to enable competitors to prepare for market entry upon expiry of the patent.

For the safe harbor provision, the key terms are "patented invention" and "reasonably related."[3] The Supreme Court had already determined that "patented inventions" as used in Section 271(e)(1) were limited to drugs, medical devices, food additives, and color additives—i.e., substances for which FDA approval was necessary—and relied on the dual distortions of the FDCA in so ruling.[4] This definition preserves the relationship between the two sections in rectifying the distortions of the FDCA. For "reasonably related," the Federal Circuit relied on the *Merck v. Integra* decision and the Federal Circuit's 2007 opinion on remand from the Supreme Court.[5] The Supreme Court held that "reasonably related" encompassed activities where a party reasonably believed that a patented compound might work through a specific process to produce a specific result and used the compound in research that would be submitted to the FDA, if successful. On remand, the Federal Circuit concluded that preclinical activities were reasonably related to FDA submissions.

In *Proveris*, Innova's activities did not qualify for the safe harbor because the patent was not a patented invention under sections 156 and 271(e)(1) and because use of the patented device was never subject to FDA approval and never qualified for patent term extension. Innova's device was not a drug, medical device, or a food or color additive. Further, it was never submitted to the FDA for approval and accordingly, the Federal Circuit found, is not eligible for safe-harbor relief.

For research tool patent holders, the key question is whether research tool patents that aren't "patented inventions" within sections 156 and 271(e)(1) may still be infringed by products that are subject to FDA approval and patent term extension. Because of the Federal Circuit's emphasis on how the two sections (156 and 271) work together to prevent distortions caused by regulatory review, the safe bet would say that if one component is missing, then the safe harbor doesn't exist. In order words, if the patent at issue is entitled to patent term extension, but the use of the patent is not reasonably related to FDA submissions, then the safe harbor will not apply. Similarly, if the patent is not eligible for term extension, but the accused products are submitted for FDA review, then the safe harbor should not apply either. Until this issue is actually before the Federal Circuit, life sciences companies should tread carefully during drug development. It may be a wiser approach to license a competitor's research tools than risk a finding that the safe harbor did not apply to your drug development activities once you've got a product ready to launch.

Footnotes

[1] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005).
[2] *Proveris Scientific Corp. v. InnovaSystems, Inc.*, -- F.3d --, No. 2007-1428, 2008 WL 29671000 (Fed. Cir. Aug. 5. 2008).
[3] Section 271(e)(1) provides a shield for making, using, offering to sell, or selling in the U.S. "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."
[4] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 672-674 (1990).
[5] *Merck KGaA v. Integra Lifesciences I, Ltd.*, 496 F.3d 1334, 1348 (Fed. Cir. 2007).