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Evolution of the Patent Infringement Safe Harbor

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Since its enactment in 1984, the scope of the "safe harbor" provision of the patent code, codified at 35 U.S.C. §271(e)(1), has been in flux. The provision is intended to exempt from infringement certain acts related to the development of drugs and medical devices that are subject to FDA regulatory approval, to enable competitors to immediately enter the market upon patent expiration. However, the contours and boundaries of the safe harbor have been a consistent source of controversy in the courts.

Although some argue that the provision was intended to provide a narrow exception to patent infringement to facilitate the development of generic drugs, many court decisions have expanded the scope of the safe harbor over time. Other appellate cases have attempted, with some success, to set limits. A recent Southern District of California decision in *Isis Pharms., Inc. v. Santaris Pharma A/S Corp.*, No. 3:11-cv-2214-GPC-KSC, 2014 U.S. Dist. LEXIS 26148, (S.D. Cal. Feb. 27, 2014), *reconsideration denied*, 2014 U.S. Dist. LEXIS 72755, suggests a renewed desire to reign in the scope of the safe harbor and set a minimum threshold for exemption.

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Evolution of the Safe Harbor

Section 271(e)(1) of the patent code was enacted in 1984 under the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act. The provision states: "It shall not be an act of infringement to make, use, or sell 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." The Federal Food, Drug, and Cosmetic Act (FDCA; http://1.usa.gov/1fxl750) is one such federal law, which requires drugmakers to submit research data to the FDA and receive regulatory approval.

The purpose of the safe harbor is to remedy two unintended "distortions" of the patent term due to federal pre-market regulatory approval requirements. *See*, *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990). The first distortion occurs at the beginning of the patent term. Because the FDA approval process often takes years to complete, new patent-holders would not be able to reap the benefit of their patents during those early years if they were required to wait for competing patents to expire before any testing or development could begin. The second distortion occurs at the end of the patent term. Without the safe harbor, patent holders would have a "*de facto* monopoly" because competing products would not be able to begin the testing and development process required for FDA approval until after the patents expire.

In construing the safe harbor provision, the Supreme Court has held that it "provides a *wide berth* for the use of patented drugs in activities related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd. (Merck I)*, 545 U.S. 193, 202 (2005) (emphasis added). Over time, several court decisions have effectively expanded the scope of the safe harbor to cover more and more conduct. In *Eli Lilly*, the Supreme Court held that the provision applies to medical devices in addition to drugs. 496 U.S. at 673-74; *see also*, *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1029 (Fed. Cir. 1997). And in *Merck I*, the Court expanded the safe harbor to exempt from infringement, under certain circumstances, preclinical research even if it is never ultimately submitted to the FDA. 545 U.S. at 205-06.

The *Merck I* court held that, as a minimum threshold, there must be a "reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect … ." *Id.* at 207. In other words, the use of patented compounds is exempt "as long as there is a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA." *Id.* at 208. On remand, the Federal Circuit held that the key inquiry is "whether the threshold biological property and physiological effect had already been recognized as to the candidate drug." *Integra Lifescience I, Ltd. v. Merck KgaA (Merck II)*, 496 F.3d 1334, 1337 (Fed. Cir. 2007).

'Reasonably Related' Requirement

Despite the general trend toward expanding the scope of the safe harbor, courts have also attempted to set limits. One way courts have narrowed the reach of section 271(e)(1) is by focusing on the requirement that exempt acts be "reasonably related to the development and submission" of information to the FDA. *Merck I*, 545 U.S. at 202. Under this requirement, "[b]asic scientific research" is

not exempt. *Id*. at 205-06. The minimum threshold for exemption, however, is less clear. For example, the Supreme Court noted in *Merck I* that experimentation on products not ultimately submitted to the FDA and the use of patented compounds in such experiments may be exempt under §271(e)(1). 545 U.S. at 206.

In *Classen Immunotherapies v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011), the Federal Circuit held that the safe harbor "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." But a year later, the Federal Circuit clarified in *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1358-59 (Fed. Cir. 2012), that the safe harbor is not restricted to pre-approval activities. The court held that the provision also exempts post-approval testing that is required by the FDA to be retained for possible inspection in order to maintain approval, noting that the FDA's requirement to maintain records satisfies the "reasonably related" requirement of §271(e)(1). *Id*.

Patented Invention Requirement

Another way some courts have attempted to limit the reach of the safe harbor is by focusing on the "patented invention" requirement. In *Eli Lilly*, 496 U.S. at 672-74, the Supreme Court held that the "patented invention" requirement under section 271(e)(1) includes at least all inventions eligible for patent term extensions under 35 U. S. C. §156. The Court stated that such construction creates "a perfect 'product' fit between the two" provisions, but acknowledged that symmetry may not exist in "relatively rare situations." *Id*.; *see also*, *Abtox*, 122 F.3d at 1028-29.

Court decisions have been mixed with respect to the safe harbor's application to research tool patents that are not extendable under §156. In *Merck I*, the Supreme Court declined to address whether the use of research tool patents to develop information related to FDA submissions is exempt under §271(e)(1). 545 U.S. at 205 n.7. On remand, the Federal Circuit majority similarly declined to address the issue, but Judge Rader responded with a sharp dissent and argued that the court's decision would have a "devastating impact on research tool inventions." *Merck II*, 496 F.3d at 1350.

In *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008), the Federal Circuit held that the safe harbor provides no relief where the patented product and the infringing product are not subject to FDA approval, even if the infringing acts are "solely for uses reasonably related" to FDA submissions. 536 F.3d 1256, 1265-66. At least one district court construed *Proveris* as excluding research tools altogether from the purview of the safe harbor. *See*, *PSN Ill., LLC v. Abbott Labs. & Abbott Bioresearch Ctr., Inc.*, 2011 U.S. Dist. LEXIS 108055, at 14 (N.D. Ill. Sept. 20, 2011).

In *Momenta*, however, the Federal Circuit emphasized that "statutory symmetry [between sections 156 and 271(e)(1)] is preferable but not required." *Momenta*, 686 F.3d at 1361 (*quoting Abtox,* 122 F.3d at 1029). The court dismissed the argument that the safe harbor is not available unless the patent is eligible for extension under section 156. *Id*. Judge Rader again dissented, noting that the court's decision will "essentially render manufacturing method patents worthless." *Id*. at 1369.

Isis v. Santaris *Suggests Renewed Desire to Narrow the Scope of the Safe Harbor*

In *Isis v. Santaris*, the Southern District of California used both the "reasonably related" and "patented invention" requirements of §271(e)(1) to deny summary judgment of noninfringement. 2014 U.S. Dist. LEXIS 26148. The case involves patents covering antisense compounds and methods. Isis alleges that Santaris, a drug discovery company also focusing on antisense technology, infringes Isis' patents by using them as "research tool[s] to identify targets and/or to screen … antisense molecules for activity inhibiting a target." *Id*. at 7. Specifically, Isis points to four commercial research and collaboration agreements between Santaris and various pharmaceutical companies. Santaris moved for summary judgment on the ground that its drug discovery services are exempt from infringement pursuant to §271(e)(1).

The court denied the motion for summary judgment on two grounds. First, the court questioned whether Santaris' drug discovery services are "reasonably related to the development and submission of information" to the FDA, noting that — at the time Santaris entered into its collaboration agreements — the specific compounds that would be used and the targets that would be modified were unknown. *Id*. at 34-37. In other words, the court's holding suggests that such drug discovery services may be akin to "basic scientific research" that does not rise to the level of exemption under §271(e)(1).

Second, the court held that the safe harbor may not be applicable to Santaris if the patents-in-suit do not constitute "patented inventions" under §271(e)(1). Because Isis' patented methods and compounds are not "themselves subject to regulatory approval," the court held that Santaris' use of such inventions was directed toward "creating its own patented inventions" rather than toward "premarketing approval of generic counterparts before patent expiration." *Id*. at 37-38.

Where is the Safe Harbor Heading?

If *Isis v. Santaris* is any indication, lower courts may continue to interpret Supreme Court and Federal Circuit cases in ways that will reign in the scope of the safe harbor. The decision may also signal that lower courts believe research tool patents deserve protection from infringement, consistent with Judge Rader's dissenting arguments in *Merck II* and *Momenta*. However, the future of protection for research tool patents remains uncertain due to persisting conflicts in the courts.

Ultimately, the scope of the safe harbor under §271(e)(1) will likely continue to fluctuate until the issue is once again taken up by the Supreme Court — which has unfortunately shown a recent tendency to cut back patent rights granted by the Federal Circuit. It remains to be seen what direction the Court will take next with respect to the scope of the safe harbor under §271(e)(1).

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