Safe Harbor: When Is Patent Infringement Not Really Infringement?

When developing new therapeutics, 35 U.S.C. § 271(e)(1) may eliminate the need to obtain licenses for patented inventions when used during of the FDA approval process.

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The development and regulatory approval of new therapeutics is a costly and difficult road to travel. If that road includes the use of patented inventions, serious roadblocks may arise if a patent license isn't available. However, in the context of the regulatory approval process, patented inventions can be used in certain circumstances without a license, and such use is not considered an act of patent infringement under the safe harbor afforded under 35 U.S.C. § 271(e)(1).

35 U.S.C. § 271(e)(1) provides:

(1) 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 (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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.

This "Safe Harbor" provision has been broadly interpreted by U.S. courts as exempting activities from patent infringement as long as the conduct is reasonably related to obtaining information relevant to the FDA approval process. The Supreme Court has also held that the phrase "patented invention" includes medical devices, color additives, and food additives in addition to drugs[1]. Activities such as using research tools, supplying active ingredients, and stockpiling drug inventories may be protected from infringement provided that there is a clear link between such conduct and efforts to secure regulatory approval. A number of U.S. courts have provided guidance on what is (and what is not) protected under the Safe Harbor provision.

For example, pre-FDA approval conduct has been found to be protected by 35 U.S.C. § 271(e)(1) as long as it is reasonably related to the development and submission of information to FDA[2]. In fact, the *Momenta* court noted that using patented compounds for developing information for FDA submission was protected by Safe Harbor even if such information was not actually submitted to the FDA. Further, the manufacturing of alleged infringing medical devices and their sales to hospitals and international distributors to support clinical trials have been found to be protected activities under the Safe Harbor[3].

At times, U.S. courts have seemingly applied the Safe Harbor exception VERY broadly; see, for example, *Edwards Lifesciences Corporation v. Meril Life Sciences Pvt. Ltd.****[4]***, involving the importation into the U.S. of two heart valve systems by Meril Life Sciences Pvt. Ltd. for a medical conference at which their activities were aimed at recruiting clinical investigators for FDA

clinical trials. The heart valve systems were never displayed or offered for sale at the conference but rather were stored in a bag in a closet/storage room. The Federal Circuit held that Meril's importation of the heart valve systems was part of its broader efforts to gain FDA approval in the U.S. The Court took the position that an exemption under § 271(e)(1) does not require the actual use of the imported devices and is not impacted by the party's intent behind the act of importation, further supporting the view that § 271(e)(1) applies irrespective of the research stage or whether the information developed is ultimately submitted to the FDA.

Judge Lourie's dissent in this case is notable, questioning whether commercial activity, which may occur simultaneously with uses reasonably related to the development and submission of information to the FDA, should still be entitled to Safe Harbor protection.

In contrast to Meril's conduct, which was part of a larger effort to seek FDA approval, the court recently in *Jazz Pharmaceuticals*[5] clarified that courts cannot enjoin pre-approval activities that may be protected under § 271(e)(1) without first determining whether those specific activities are infringing. There, the court reversed a district court injunction that barred Avadel from initiating any future clinical trials for its product, activities which had not been alleged or proven to be infringing, holding that § 271(e)(3) prohibits such forward-looking injunctions absent a finding that Safe Harbor does not apply.

Turning to the other end of the regulatory timeline, courts have held that the Safe Harbor can, in certain instances, cover post-approval activities. For example, the Federal Circuit held that the Safe Harbor provision applies to "non-routine" activities performed to satisfy specific FDA requirements, such as use of a patented method in research submitted to the FDA for the purpose of obtaining a labeling change[6], but does not apply to "routine" post-approval submissions to FDA, such as quality control testing[7].

While powerful protection, the Safe Harbor doctrine does have its limits. "Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not 'reasonably related to the development and submission of information' to the FDA[8]." In *Isis Pharms. v. Santaris Pharma A/S Corp.*[9], the court held that the use of patented methods to identify targets or screen molecules for activity was not protected by the Safe Harbor doctrine because the alleged infringer did not have a reasonable basis for believing the compounds it was screening would have a particular biological effect through a particular biological process.

In summary, the Safe Harbor may reduce costs associated with obtaining regulatory approval by eliminating the need to obtain licenses for patented inventions used as part of the FDA approval process. Of course, with the exceptions noted above, these protections cease once approval is granted, requiring a fresh assessment of potential infringement issues.

For more information, please contact patent attorney Lisa Warren.

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[1] Eli Lilly & Co. v. Medtronic, 496 U.S. 661, 671 (1990)

[2] *See*, Momenta Pharms., Inc. v. Amphastar Pharms., Inc. 686 F.3d 1348, 1352-53 (Fed. Cir. 2015)

[3] *See*, Intermedics, Inc. v. Ventritex, Inc.,775 F. Supp. 1269 (N.D. Cal. 1991)

[4] Edwards Lifesciences Corp. v. Meril Life Sciences Pvt. Ltd., 96 F.4th 1347 (Fed. Cir. 2024)

[5] Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 136 F.4th 1075 (Fed. Cir. 2025).

[6] Classen Immunotherapies v. Elan Pharms., 786 F.3d 892, 897 (Fed. Cir. 2015)

[7] Momenta Pharms. v. Teva Pharms. U.S.A., 809 F.3d 610 (Fed. Cir. 2015).

[8] *See*, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205-06 (2005)

[9] Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 3:11-cv-2214-GPC-KSC, 2014 WL 794811 (S.D. Cal. Feb. 27, 2014)